UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

BOARD OF EDUCATION OF JOLIET TOWNSHIP HIGH SCHOOL DISTICT 204; BOARD OF EDUCATION OF EAST AURORA, DISTRICT 31; BOARD OF EDUCATION OF THORNTON TOWNSHIP HIGH SCHOOLS, DISTRICT 205; BOARD OF EDUCATION OF THORTON FRACTIONAL TOWNSHIP HIGH SCHOOL, DISTRICT 215; THE BOARD OF EDUCATION OF BOARDMAN LOCAL SCHOOLS; BOARD OF EDUCATION OF LIBERTY PUBLIC SCHOOLS; BOARD OF EDUCATION OF BARBERTON LOCAL SCHOOLS; BALTIMORE CITY BOARD OF SCHOOL COMMISSIONERS; EUNICE COUNTY PUBLIC SCHOOLS; GALLUP-MCKINLEY COUNTY PUBLIC SCHOOLS; SUSANVILLE ELEMENTARY SCHOOL; LASSEN COUNTY OFFICE OF EDUCATION; REGIONAL SCHOOL UNIT 34 BOARD OF EDUCATION; BOARD OF EDUCATION OF PORTLAND SCHOOL DEPARTMENT; PUTNAM COUNTY SCHOOL DISTRICT; ROCHESTER CITY SCHOOL DISTRICT; BOARD OF ORLEANS-NIAGARA BOARD OF COOPERATIVE EDUCATIONAL SERVICES;

FOR THEMSELVES AND OTHERS SIMILARLY SITUATED,

Plaintiffs,

vs.

PUBLICIS HEALTH, LLC; PRACTICE

Case Number _____

FUSION, INC.; VERADIGM, INC., f/k/a ALLSCRIPTS HEALTHCARE SOLUTIONS, INC.; and ZS ASSOCIATES, INC.

Defendants.

ORIGINAL COMPLAINT

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I. INTRODUCTION

1. For two decades now, the modern[1] opioid crisis has raged. In 2017, the President of the United States announced a public health emergency. In August 2023, drug-overdose deaths in the United States peaked at 111,415 annual deaths for the 12-month ending period.[2] Drug overdoses now kill more than 100,000 Americans per year – more than vehicle crash and gun deaths combined.[3] Today, there are fewer and fewer Americans whose lives have not been scarred by the epidemic.

2. History repeats itself not through accident or accretion, but through affirmative acts undertaken by those who wish it so. The modern opioid epidemic has a cause, and this complaint seeks to hold accountable principal participants in its creation and propagation. The modern opioid epidemic began with the introduction and expansive promotion of OxyContin by Purdue Pharma in 1996 and was driven thereafter by industry-wide marketing efforts in which Defendants were principal and knowing participants. It continues to rage today.

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[1] Throughout history, instances of widespread availability of opioids causing severe detriment to all of us are legion. To begin with, the drug was powerful enough to be used as a means of colonial expansion by the British Empire in China. There were two Opium Wars. *See* W. Travis Hanes III & Frank Sanello, *The Opium Wars: The Addiction of One Empire and the Corruption of Another*, 2002; Julia Lovell, *The Opium War: Drugs, Dreams, and the Making of Modern China*, 2011.

More recently, the United States has experienced previous waves of opioid abuse. "The first was in the early 1900's, when heroin was marketed alongside Bayer aspirin as a remedy for numerous minor ailments." Dr. Anna Lembke, *Drug Dealer, M.D.*, Johns Hopkins University Press (2016), Pg. 57. A second heroin epidemic struck the United States during the Vietnam War. *Id*. *See also* John Fauber et al., "A Look Back: Abandoned Painkiller Makes a Comeback," *Medpage Today*, June 9, 2017, *available at*: https://www.medpagetoday.com/psychiatry/addictions/65916 (describing the removal of Numorphan, an oxymorphone product, from the market in the 1970's in response to widespread abuse).

Throughout the time-period relevant to this complaint, the dangers of widespread opioid availability weren't just common knowledge, they were historical fact.

[2] Provisional Drug Overdose Death Counts, Centers for Disease Control National Health Statistics , *available at*: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

[3] Betsy McKay, "U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids," *Wall Street Journal*, July 14, 2020, *available at*: https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200

3. The pharmaceutical industry is complex and highly regulated. Drug manufacturers cannot, and do not, do everything on their own. These companies endeavor to research, develop, obtain approval, and bring to market products that improve the health and livelihood of hundreds of millions of people worldwide. Because the scale of the industry is vast, the stakes – both in terms of potential profit and impact on human lives – are high, and the industry's complexity byzantine. From cutting-edge medical and scientific research, to navigating the state and federal regulatory environment, to marketing their drugs in a responsible manner to prescribers and the consuming public, the demands on a traditional pharmaceutical manufacturer are multi-faceted, ever-present, and continuously changing.

4. The reality is pharmaceutical manufacturers routinely rely on third parties to design, implement, and oversee projects and workflows to achieve mission-critical tasks. Given the complexity of the industry, there are numerous companies that find their niche in offering core services to pharmaceutical manufacturers that are critical to the success of the manufacturers' operations but are not performed by the manufacturer alone. These third parties are necessary components of the drug manufacturing and sales industry as a whole.

5. Manufacturers do not rely on these third-party providers on a one-off basis, but instead rely on these companies again and again to design and implement measures to achieve specific needs. The relationships are recurring and long-term.

6. Defendants are three such companies. McKinsey & Company, Inc. is another. Defendants worked intimately with McKinsey and McKinsey's clients on these same efforts to maximize the volume of opioids sold in the United States, and did so for decades.

7. Publicis and ZS routinely advise multiple pharmaceutical manufacturers and operationalize the sales and marketing of competing products, such as branded extended-release

opioids, and do so contemporaneously. Further, it is common for third-party consultants such like Publicis and ZS often sell the same strategy to multiple clients, and to assist with ongoing implementation of those strategies after clients have accepted Defendants' suggestions. And in many instances, these third-party providers are larger companies than the clients that they advise. Accordingly, these Defendants act as the connective tissue binding the sales and marketing strategies of competing firms selling similar products; in this case, Schedule II controlled substances.

8. One Defendant here – Publicis – is the largest advertising agency on Earth. Publicis Groupe S.A. is the French parent of Defendant Publicis Health LLC ("Publicis"). The second defendant here– ZS – Defendant is a little known, but principal architect of the sales and marketing efforts that begat the opioid crisis. The third, Practice Fusion, Inc. ("Practice Fusion"), offered a unique channel through which the marketing messages and strategy created by co-Defendants could be delivered to the intended audience: healthcare providers, the folks with prescription pads in their hands. All Defendants were crucial contributors to the architecture and functioning of the opioid marketplace.[4]

9. McKinsey & Company, Inc. – the global management consultancy – is another third party provider and the subject of separate and ongoing litigation regarding its own involvement in the opioid crisis. Defendants worked intimately with McKinsey and McKinsey's clients on the same efforts and projects to maximize the volume of opioids sold in the United States, and did so for decades.

10. Defendants – alongside and with McKinsey – played a central role in the unfolding, propagation, and exploitation of the opioid crisis by advising multiple opioid manufacturers and

[4] Veradigm, Inc., f/k/a Allscripts Healthcare Solutions, Inc. ("Allscripts") is the parent company of defendant Practice Fusion.

other opioid marketplace participants how to sell as many opioids as conceivably possible. Knowing that their clients' products were highly addictive, ineffective, and unsafe for the treatment of long-term chronic pain, non-acute pain, and non-cancer pain, Defendants focused singularly on maximizing opioid sales, no matter the resultant cost to society. They did this for well over a decade, despite knowing full well the risks to public health and safety and the widespread economic harm from transforming Schedule II controlled substances into top-selling blockbuster drugs.

11. The purpose of Defendants' work with their opioids clients was at all times to maximize return on investment. The whole point for their clients (and hence Defendants) was to make as much money as possible. They all did. This relentless drive to increase sales and create greater availability of opioids was made with no concern about the parallel, known, and inevitable increase in opioid-related deaths, addiction, abuse, diversion, and misuse.

12. The deceptive marketing strategies that Defendants and their clients invented, developed, deployed, and continually refined for years to expand the market for opioids are foundational to the epidemic.

13. Defendants worked hand-in-hand with major opioid manufacturers, including Purdue Pharma L.P., Endo Pharmaceuticals,[5] Johnson & Johnson,[6] and Mallinckrodt,[7] and Teva[8] for years. At the same time, Defendants Publicis, ZS, and Practice Fusion endeavored alongside McKinsey, shoulder-to-shoulder and in common cause with McKinsey and their manufacturer clients to perpetuate and greatly increase in size the opioids market; to sell more and more pills.

[5] "Endo Pharmaceuticals" or "Endo" refers to Endo Health Solutions Inc., Endo International plc, and Endo Pharmaceuticals Inc., collectively.
[6] "Johnson & Johnson" refers to Johnson & Johnson Services, Inc. and its wholly-owned subsidiary Janssen Pharmaceuticals, Inc. ("Janssen").
[7] "Mallinckrodt" refers to Mallinckrodt LLC and Mallinckrodt plc, together.
[8] "Teva" refers to Teva Pharmaceutical Industries Ltd. as well as Cephalon, Inc.

14. Publicis is one of the "Big Four," the four firms that account for more than half of the global advertising industry. In 2002, as the opioid crisis was taking root across the United States, the president of the American Association of Advertising Agencies, stated, "Now you have four megacompanies with revenues that are staggering, bigger than some of the companies they serve."[9] The rise of the Big Four came through decades of mergers and acquisitions of separate agencies; each is essentially a conglomerate. By October of 2021, Publicis had risen to become the largest advertising conglomerate in the world, with a market capitalization in excess of $16 billion.[10]

15. Publicis has acquired and developed particular expertise in serving the pharmaceutical industry. Publicis – through its myriad divisions – serves multiple pharmaceutical manufacturers in advertising their drugs. It relies on the healthcare sector for approximately 13% of its approximately $14 billion in annual revenue, making it one of the largest industry sectors by revenue for the conglomerate.[11]

16. The over-marketing of opioids – schedule II controlled substances that are *controlled* because they are known to be addictive and deadly – was the wellspring of the opioid crisis in this country. Although the introduction of OxyContin by Purdue Pharma L.P. ("Purdue") in the late 1990's is widely acknowledged as a precipitating cause of the opioid crisis, Purdue was not the only pharmaceutical company to enthusiastically foment and exploit the booming market of controlled substances used for the treatment of pain. An industry-wide sales and marketing effort was deployed over the years by numerous manufacturers of opioid medications in order to maximize the amount of opioids they could sell.

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[9] Stuart Elliott, Advertising's Big Four: It's Their World Now, *New York Times*, March 31, 2002, *available at*: https://www.nytimes.com/2002/03/31/business/advertising-s-big-four-it-s-their-world-now.html

[10] *See https://www.prweek.com/article/1731568/publicis-overtakes-rivals-worlds-valuable-agency-group*

[11] *See* http://documents.publicisgroupe.com/resultat2021/Presentation-H1-2021-RESULTS.pdf at 15.

17. The sales and marketing efforts to sell opioids to as many individuals as possible, even when they were known to be addictive, were not solely designed by the manufacturers themselves, nor did the manufacturers implement these tactics on their own. Rather, pharmaceutical manufacturers routinely relied on Defendants to design and implement crucial aspects of the sales and marketing strategies used to sell opioids.

18. Publicis did not produce mere copy. Publicis not only designed these sales and marketing campaigns for numerous opioid manufacturers, it also worked in identifying the optimal targets for the different messages Publicis delivered on behalf of its clients. In many instances, pharmaceutical manufacturers would outsource practically the entire business of selling its drugs. Through Publicis Touchpoint Solutions, Publicis provided entire sales forces on a contract basis to be used by their manufacturer clients to detail prescribers.

19. Nor was Publicis merely some ancillary vendor. Because of its partnerships with multiple clients selling competing branded opioid products contemporaneously, Publicis's role was unique. It served as a hub, aggregating knowledge of what numerous competitors within the industry were doing with respect to designing sales and marketing campaigns, contemporaneously. Indeed, Publicis worked with industry-wide groups to address challenges that the entire opioids industry faced and compiled invaluable insights and business intelligence which it commoditized by providing it to numerous clients.

20. As a hub, Publicis also connected opioid manufacturers to specialist vendors, such as Defendant Practice Fusion, which worked with Publicis and Purdue to target and deliver content to healthcare providers designed to increase the amount of Purdue's opioids sold through Practice Fusion's proprietary software platform used in doctors' offices across the country.

21. ZS is a private consulting company that specializes in the pharmaceutical industry. It was founded in 1983 by two professors at the eminent Kellogg School of Business at Northwestern University. Since then, ZS has achieved substantial growth, and now employs thousands of consultants and enjoys hundreds of millions of dollars in annual revenue. "ZS" is the initials of the two founders, Professors Andris Zoltners and Prabhakant Sinha. In 2022, annual revenue for ZS was reported to be approximately $2 billion, and ZS currently employs in excess of 12,000 professionals.[12]

22. In particular, ZS specializes in providing critical pharmaceutical sales and marketing services to drive increased sales volume and related profits.

23. As set forth in this complaint, Defendants' purpose in working with these companies was plain and singular: to maximize profits for their clients by making sure that every dollar spent on sales and marketing of opioids generated as many sales of these addictive controlled substances as possible. Maximizing profits and revenue for Defendants' clients was achieved by maximizing the total volume of opioids sold. McKinsey, Publicis and ZS applied their sales and marketing acumen to multiple opioid brands on behalf of numerous manufacturer clients, and often at the same time. McKinsey, Publicis and ZS were common denominators throughout.

24. These Defendants played a central role in the creation, prolongation, and exploitation of the opioid crisis for money. As the alarm bells sounded repeatedly in the early years of the unfolding crisis, Defendants continued their work with opioid manufacturers unabated and with alacrity, and for decades, as the bells rose to cacophony. It continued right up until the bitter end.[13]

[12] *See* https://www.zs.com/about/offices

[13] For instance, ZS had an active contract with Purdue Pharma L.P. ("Purdue") to assist with the sales and marketing of OxyContin in 2018, after Purdue had already pled guilty, settled numerous prior lawsuits brought by the DOJ, state

25. Moreover, the work was conducted in the shadows. Defendants treat their client relationships as confidential. Classically, ZS or Publicis – like McKinsey – work behind the scenes and do not publicize its work. Until recent consultant litigation, the public had essentially no knowledge or awareness of the extent of Defendants' involvement in tearing apart our social fabric for profit. Plaintiff school districts, with their eyes now fully open to the true scope of the origins and prolongation of the opioid crisis, seek to hold all those responsible accountable.

26. American public schools perform an indispensable function, central to the health of American democracy, by providing free education to every student who comes through their doors. But in recent decades, public schools' ability to succeed has been taxed by the devastation of the opioid epidemic.

27. The connection between Defendants' efforts to maximize sales of opioids alongside their opioid manufacturer clients and the substantial harms incurred by public schools is direct and proximate. As a result of Defendants' actions, the market was flooded with opioids, and the number of women using opioids during pregnancy increased, as did the number of women giving birth to infants born with Neonatal Opioid Withdrawal Syndrome ("NOWS"). NOWS is a group of adverse neurodevelopmental conditions that occur when infants are born with opioid withdrawal symptoms.[14] Four or five years after birth, those children enter the schools. Because of adverse neurodevelopmental consequences of NOWS, they disproportionately need and receive mandated costly "special education" services often from pre-kindergarten all the way through high school. 34 C.F.R. §§ 300.320-300.328. The average per pupil expenditure on special education services is

Attorneys General and individuals and faced a new wave of similar litigation. That year, with its contract with ZS still active, Purdue chose to disband its sales force and cease marketing the drug altogether.

[14] Neonatal Opioid Withdrawal Syndrome ("NOWS") is also referred to as Neonatal Abstinence Syndrome ("NAS"). For present purposes, the two labels—NOWS and NAS—refer to the same diagnosed medical condition.

almost twice the per pupil cost of other students.[15] By maximizing the sales of opioids in the face of a national epidemic, Defendants increased NOWS births, saddling many public schools with large, increased, and unfunded costs.

28. The effect of Defendants' efforts to increase opioid sales has been staggering. Between 1999 and 2014, the number of women using opioids during pregnancy increased by 333%.[16] By 2017, the estimated NAS rate was 7.3 per 1,000 hospital births, with ongoing increases during the [COVID-19] pandemic.[17] A newborn is now diagnosed with NOWS every 15-25 minutes in the United States.[18] The incidence of NOWS increased more than fivefold among infants covered by Medicaid.[19] The financial and other consequences for public schools as a result of the increased incidence of NOWS have been very serious, and were foreseeable.

29. For years, research has reported that fetal exposure to opioids can produce adverse chances in brain structure and function.[20] And the link between those problems and educational

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[15] Jay G. Chambers et al., *Total Expenditures for Students with Disabilities, 1999-2000: Spending Variation by Disability*, Special Education Expenditure Project 4 (June 2003), https://www.air.org/sites/default/files/SEEP5-Total- Expenditures.pdf.

[16] Sarah C. Haight et al., *Opioid Use Disorder Documented at Delivery Hospitalization - United States, 1999-2014*, 67 Morbidity and Mortality Weekly Report 845, 846 (2018).

[17] Chasnoff IJ, Seiger ML (2023) *Prenatal Opioid Exposure and Special Education Needs: A Sibling Study*, Adv Pediatr Res. 10:069

[18] Saminathan Anbalagan & Magda D. Mendez, *Neonatal Abstinence Syndrome* (2021), https://www.ncbi.nml.nih.gov/books/NBK551498/.

[19] Tyler N.A. Winkelman et al., *Incidence and Costs of Neonatal Abstinence Syndrome Among Infants With Medicaid: 2004-2014*, 141 Pediatrics e20173520 (2018).

[20] *See generally,* Emily J. Ross et al., *Developmental Consequences of Fetal Exposure to Drugs: What We Know and What We Still Must Learn*, 40 Neuropsychopharmacology 61, 76 (2015) (discussing research results dating back to 1994).

outcomes is not surprising: there is a direct relationship between infants born with NOWS and the need for special education and related services once these children are in school.[21]

30. Indeed, a sibling study comparing opioid-exposed children with siblings in the same household who were *not* exposed shows the stark burden placed on schools by the incidence of NOWS: 50.1% of opioid-exposed children used at least one service (special education, 504 plan, or behavioral service), compared to only 27.9% of biological siblings and 11.6% of non-biological siblings. Opioid-exposed children "were enrolled in [specific school-based services] at significantly higher rates than non-exposed biological or non-biological siblings."[22]

31. In addition, the need for additional services because of the opioid epidemic is not limited to children born with NOWS. Many children living in households battling addiction require additional services as well. Children from homes with opioid-abusing parents, other caregivers, or siblings are at risk for a wide variety of adverse outcomes, even if they were not exposed to opioids in utero.[23]

32. The opioid epidemic has required many public school districts, including Plaintiffs, to expend and divert already scarce resources to support children born with NOWS or whose families are struggling with addiction and death. These students disproportionately require mandated special education and related services or present behavioral and emotional challenges that disrupt classrooms, thereby burdening schools.

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[21] Mary-Margaret A Fill et al., *Educational Disabilities Among Children Born With Neonatal Abstinence Syndrome*, 142 Pediatrics e20180562 (2018); *see also* Ju Lee Oei et al., *Neonatal Abstinence Syndrome and High School Performance*, 139 Pediatrics 2 (2017).

[22] Chasnoff, IJ, Seiger ML (2023) *Prenatal Opioid Exposure and Special Education Needs: A Sibling Study*, Adv Pediatr Res. 10:069.

[23] Gemma Sanjuan Herranz et al., *Children Born to Heroin-Addicted Mothers: What's the Outcome 25 Years Later*, 5 J. Addiction Res. & Therapy 180 (2014).

II. JURISDICTION AND VENUE

33. At all times relevant hereto, Defendants engaged in the business of researching, designing, and implementing marketing and promotional strategies – as well as other strategies – with the intent of maximizing overall opioid sales for and with various opioid marketplace participants in the State of Illinois and within this district.

34. This court has personal jurisdiction over Defendants because they carry on a continuous and systematic part of their general businesses within Illinois, maintaining substantial business interests within Illinois, have transacted and regularly transact business in Illinois, and have caused harm in Illinois as a result of the specific business activities complaint of herein.

35. This Court has jurisdiction over Defendants due to Defendants' conduct in this district and throughout Illinois. Defendants have deliberately engaged in significant acts and omissions within Illinois that have injured Plaintiffs. Defendants purposefully directed their activities at this district and its citizens, and the claim arise out of those activities.

36. Additionally, Defendant ZS is a domestic Illinois corporation headquartered in Evanston, Illinois. Defendant Veradigm, Inc. is a Delaware corporation headquartered in Chicago, Illinois.

37. Venue is proper in in the United Stated District Court for the Northern District of Illinois because a substantial part of the events giving rise to Plaintiffs' claims occurred in, were directed to, and/or emanated from this District. 28 U.S.C. § 1391(b).

III. PARTIES

38. Plaintiffs Board of Education of Joliet Township High School, District 204; Board of Education of East Aurora, District 205; Board of Education of Thorton Fractional Township High School, District 215, on behalf of themselves and all other independent school districts in the State of Illinois.

39. Plaintiffs Board of Education of Boardman Local Schools, Board of Education Liberty Local Schools, and Board of Education Barberton Local Schools, on behalf of themselves and all other independent school districts in the State of Ohio.

40. Plaintiff Baltimore City Board of School Commissioners, on behalf of itself and all other independent school districts in the State of Maryland.

41. Plaintiffs The Board of Education of Eunice Public Schools and Gallup McKinley County Schools, on behalf of themselves and all other independent school districts in the State of New Mexico.

42. Plaintiffs Lassen County Office of Education and Susanville School District, on behalf of themselves and all independent school districts in the State of California.

43. Plaintiffs Regional School Unit 34 Board of Education and Board of Education of Portland School Department, on behalf of themselves and all other independent school districts in the State of Maine.

44. Plaintiff Putman County School District, on behalf of itself and all other independent school districts in the State of Florida

45. Plaintiffs Rochester City School District and Board of Orleans-Niagara Board of Cooperative Educational Services, on behalf of themselves and all other independent school districts in the State of New York.

46. Defendant Publicis Health, LLC ("Publicis Health") is a Delaware limited liability company with its principal place of business in New York City. Additionally, Publicis maintains an office within the district at 35 W. Wacker Drive, Chicago, IL 60601, and is registered to do business in Illinois. It may be served with process through its registered agent, CT Corporation Company, 208 So. LaSalle St., Ste. 804, Chicago, IL 60604.

47. Defendant Practice Fusion, Inc. ("Practice Fusion") is a Delaware corporation with its headquarters in San Francisco, California. It may be served with process through its registered agent, National Registered Agents, Inc. located at 818 West Seventh St., Ste 930, Los Angeles, CA 90017. Practice Fusion provided electronic health records ("EHR") services to clinicians and healthcare providers, and was ultimately acquired by Defendant Allscripts.

48. Defendant Veradigm, Inc. f/k/a Allscripts Healthcare Solutions, Inc. ("Allscripts") is a Delaware corporation with its headquarters in Chicago, Illinois. On February 13, 2018, Allscripts completed a merger whereby it acquired Defendant Practice Fusion and became a successor in interest thereto. It may be served with process through its registered agent, CT Corporation Company, 208 So. LaSalle St., Ste. 804, Chicago, IL 60604.

49. Defendant ZS Associates, Inc., is an Illinois corporation with its principal office located at 1800 Sherman Avenue, Evanston, Illinois 60201. It may be served with process through its registered agent, Illinois Service Corporation, 801 Adlai Stevenson Dr., Springfield, IL 62703.

IV. FACTUAL ALLEGATIONS

50. This complaint will tell the individual stories of each defendant, beginning with Publicis, then Practice Fusion, and finally ZS, and will detail each defendant's interactions with multiple opioid manufacturers – as well as each other and McKinsey – in turn. Each worked for the same opioid manufacturers at the same time and on the same projects, and all were unified in their common purpose[24]: to maximize opioid sales and associated profits for the past two decades.

[24] *See* "McKinsey on Implementation," McKinsey & Company Inc., April 30, 2017, *available at*: https://www.youtube.com/watch?v=rEQOGVpl9CY ("One thing intriguing about the engagements is that they often have a common purpose, and a genuine cause," Josh, a Senior Implementation Coach at McKinsey, explained.)

A. The Opioid Crisis

51. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

52. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

53. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911: "The habit has this nation in its grip to an astonishing extent . . . Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."

54. Pharmaceutical companies have long tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and

cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the United States was limited to prescription only in 1914 and then banned altogether a decade later.

55. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

56. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the Drug Enforcement Administration since 1970.

57. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

58. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

59. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, twelve hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic

pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately four to six hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The opioid manufacturers promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

60. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration and, at very high doses, can, and often do, arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

61. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

62. As one doctor put it, the widespread long-term use of opioids "was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

63. The results were devastating, and the nation continues to reach ever grimmer milestones. In 2020, drug-overdose deaths in the United States soared nearly 30%, reaching all-time highs.[25]

B. Selling Controlled Substances: Marketing and the Origins of the Opioid Crisis

64. Selling drugs is big business:

> Perhaps the most powerful tool that pharmaceutical companies have for driving up profit margins and cultivating growth of drug markets is advertising. Pharmaceutical companies, especially the makers of opioid prescriptions, spend an enormous amount of money advertising their products – far more than they ever spend on drug research and development (Swanson 2015). In 2012 alone, the US pharmaceutical industry spent more than $27 billion on drug promotion – including more than $24 billion on marketing directly to physicians and $3 billion advertising to consumers.[26]

65. Professor Amanda Pustilnik of the Center for Law, Brain, & Behavior, a former McKinsey & Company management consultant, emphasized the centrality of the role coordinated opioid sales and marketing played in creating the opioid crisis. "[T]he story of the opioid epidemic is often misrepresented as a story of irresponsible patients and over-prescribing doctors." Referring to a recent lawsuit brought by the State of Massachusetts against Publicis, Professor Pustilnik identified a more pernicious cause: the efforts by defendants to change prescriber behavior. "[T]his prosecution gets at the heart of the matter. Patients and doctors were not, on average, irresponsible.

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[25] Betsy McKay, "U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids," *Wall Street Journal*, July 14, 2020, *available at*: https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200.

[26] Melina Sherman, "Opiates for the masses: constructing a market for prescription (pain)killers," *Journal of Cultural Economy*, Vol. 10, Issue 6, 2017, *available at*: https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010 (*citing* Swanson, Ana, 2015. Big pharmaceutical companies are spending far more on marketing than on research. *The Washington Post*, February 11, *available at*: https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/; Cegedim Strategic Data, 2013. *2012 U.S. pharmaceutical company promotion spending*. In the Pew Charitable Trust (2013), *Fact Sheet: Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, *available at*: https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients).

They acted under the influence of a concerted plan of misinformation and over-promotion orchestrated up and down the supply chain for these medications."[27]

66. Defendants, along with Professor Pustilnik's former employer, were members of the concert and enterprise that devised and executed the plan Professor Pustilnik identified as a primary source of the opioid crisis.

67. Although the introduction of OxyContin by Purdue Pharma in the late 1990's is widely acknowledged as a precipitating cause of the opioid crisis, Purdue was not the only pharmaceutical company to enthusiastically foment and exploit the booming market of controlled substances used for the treatment of pain. An industry-wide sales and marketing effort was deployed over the years by numerous manufacturers of opioid medications in order to maximize the amount of opioids they could sell.

68. As referenced above, OxyContin, the principal product of the Sackler family's Purdue Pharma L.P., was introduced to the market in 1996. Within six years of its introduction, the increasingly widespread misuse and abuse of OxyContin and similar opioids had drawn the attention of the United States Senate.

69. Two decades ago, Dr. Art Van Zee traveled from the rural coal town of St. Charles, in the southwestern corner of Virginia, to Washington D.C. to provide testimony to the United States Senate Committee on Health, Education, Labor and Pensions. On February 12, 2002, that Committee held a hearing entitled "Examining the Effects of the Painkiller OxyContin, Focusing on Federal, State, and Local Efforts to Decrease Abuse and Misuse of this Product While Assuring Availability for Patients Who Suffer Daily from Chronic Moderate to Severe Pain."[28]

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[27] Thomas F. Harrison, "Novel Opioid Lawsuit Goes After Ad Agency," Courthouse News, May 6, 2021, *available at:* https://www.courthousenews.com/novel-opioid-lawsuit-goes-after-ad-agency/.

[28] A transcript of the hearing is *available at*: https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm

70. In those early days of the unfolding opioid epidemic, Dr. Van Zee's medical practice in St. Charles put him in a position to offer informed, first-hand observations of the toll that the pharmaceutical industry's efforts to market opioids was exacting from his community. He testified:

> In the 25 years I have practiced as a general internist in St. Charles, which is a small Appalachian coal mining town, there has never been anything to compare to the epidemic of drug abuse and addiction that we have seen the last 3 years with OxyContin. Contrary to what is sometimes portrayed in the media as long-term addicts switching to the drug *du jour*, what we have seen for the most part is numerous young people recreationally using OxyContin and then becoming very rapidly addicted. Many of these kids are good kids, good families with bright, promising futures that are being destroyed in every way by their opioid addiction.[29]

Further, Dr. Van Zee identified the sales and marketing practices of the pharmaceutical industry when selling controlled substances as a primary cause of the problem:

> My own personal view of the complicated OxyContin abuse problem is that there are at least three major elements involved. First, there has been an obvious problem with physician misprescribing and overprescribing of this drug. Second, this epidemic has been a vicious indicator of the alarming degree of prescription drug abuse in our society. **Third and perhaps the one closest to this committee and the FDA is that the promotion and marketing of OxyContin by Purdue Pharma has played a major role in this problem.**[30]

71. Five years after Dr. Van Zee's testimony and 80 miles from his hometown of St. Charles, United States Attorney John Brownlee announced in Abingdon, Virginia, the guilty plea of the Purdue Frederick Company, the parent of Purdue Pharma, L.P., relating to the misbranding of OxyContin. Brownlee stated, "Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse,

[29] *See* https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm
[30] *Id*. (emphasis added).

and less likely to cause withdrawal. In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less subject to abuse, and less addictive than other pain medications on the market."[31]

72. Along with the guilty plea, Purdue agreed to a Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services. For a period of five years, ending in 2012, Purdue was obligated to retain an Independent Monitor and submit annual compliance reports regarding its marketing and sales practices and training of sales representatives vis-à-vis their interactions with health care providers.

73. Two years later, in 2009, Dr. Van Zee published *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy* in the American Journal of Public Health. As the title suggests, the paper applied formal rigor to some of the personal observations Dr. Van Zee previously provided to the US Senate in 2002.

74. In his 2009 paper, Dr. Van Zee stated the matter plainly: "Compared with noncontrolled drugs, controlled drugs, with their potential for abuse and diversion, pose different public health risks when they are overpromoted and highly prescribed."[32] In one sense, Dr. Van Zee's observation is not particularly novel. Indeed, it approaches tautology: controlled substances are *controlled* precisely because they should not be sold to maximize volume and profits. This did not prevent Purdue and ZS from marketing its opioids full hilt, however. By 2004, "OxyContin had become the most prevalent prescription opioid in the United States."[33]

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[31] *See* the May 10, 2007, News Release from United States Attorney, John Brownlee at https://media.defense.gov/2007/May/10/2001711223/-1/-1/1/purdue_frederick_1.pdf

[32] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, American Journal of Public Health, February 2009, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf

[33] *Id.*

75. Dr. Van Zee identified the three principal marketing tactics Purdue employed as a source of OxyContin misuse and abuse and suggested that regulation may be appropriate to curtail its use. The first was the use of granular sales and marketing data to profile individual prescribers to identify those that already prescribe large amounts of opioids. "Through these profiles, a drug company can identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country. One of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country."[34]

76. The second tactic was the use of incentive compensation structures to encourage the salesforce to sell ever more prescriptions of OxyContin. Bonuses at Purdue were "uncapped," meaning there was no upper limit to what an OxyContin salesperson could earn. Rather, salesforce remuneration was a direct function of overall OxyContin sales – the more you sell, the more you make. "A lucrative bonus system encouraged sales representatives to increase sales of OxyContin in their territories, resulting in large numbers of visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign aimed at them."[35]

77. The third tactic was to increase the overall number of individual calls that the salesforce placed to prescribers. "From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671, and its total physician call list from approximately 33,400 to 44,500 to approximately 70,500 to 94,000 physicians."[36]

78. When combined, these tactics produced the intended result. "The use of prescriber profiling data to target high-opioid prescribers – coupled with very lucrative incentives for sales

[34] *Id.*
[35] *Id.*
[36] *Id.*

representatives – would seem to fuel increased prescribing by some physicians – perhaps the most liberal prescribers of opioids and, in some cases, the least discriminate."[37]

79. Dr. Van Zee's 2002 and 2009 observations regarding the direct link between OxyContin marketing and overall opioid overdose mortality would, in time, be confirmed by further academic work, including empirical research published by the National Bureau of Economic Research in 2019.

80. Moreover, the legal regime under which the opioid drugs Publicis assiduously marketed and sold are regulated is the *Controlled* Substances Act. Publicis sought to maximize the sales of drugs known to be dangerous and addictive, and whose manufacture and distribution accordingly require *control*, not the same marketing tactics otherwise used for non-addictive products whose abuse liability does not routinely cause the user's death.

81. In 1970, Congress enacted the Controlled Substances Act ("CSA") in order to combat the spread and use of drugs known to be dangerous and/or addictive. It is also the legal regime that regulates the lawful production, possession, and distribution of substances deemed deserving of control, but that have some recognized medical use.

82. The Drug Enforcement Administration ("DEA") administers the act. The CSA allocates substances meriting control to one of five classifications based on the characteristics of each substance and the attendant risks posed.

83. In order to produce and market certain substances meriting control, pharmaceutical companies must register with the DEA and be bound by the reporting requirements of the CSA. The act requires any person who seeks to manufacture, distribute, dispense, or conduct research

[37] *Id.*

involving any controlled substance to obtain and maintain a registration from the DEA. *See* 21 U.S.C. § 823(e); 21 C.F.R. § 1301.74(b).

84. The opioids that Defendants and their clients marketed are classified as Schedule II controlled substances under the CSA. Schedule II substances "have a high potential for abuse for which may lead to severe psychological or physical dependence."[38] As such, opioids are subject to control under the CSA because the diversion of these substances poses recognized risks to public health and safety.

85. The CSA also imposes reporting requirements on manufacturers, whereby registrants must monitor and report suspicious orders of opioids. These obligations include recordkeeping, whereby registrants must maintain complete and accurate inventories and records of all transactions involving controlled substances and make those records available to the DEA. In addition, registrants must periodically report all sales, delivery, disposal, or dispensing activities of any controlled substance. Schedule II controlled substance manufacturers, such as Publicis' clients, must also file Automated Reports and Consolidated Orders System (ARCOS) reports with the DEA.

86. Upon information and belief, Defendants, through their efforts to increase opioid sales for its clients, possessed and shared with its clients detailed information on the prescribing and dispensing patterns and volumes of its clients' Schedule II opioids. Upon information and belief, McKinsey, Publicis and ZS could determine when the prescribing or dispensing of a given clients' opioid product was unusual. For instance, upon information and belief, McKinsey, Publicis and ZS clients could identify aberrations in the number of units sold, doses prescribed,

[38] *See* Drug Scheduling, United States Drug Enforcement Administration, *available at*: https://www.dea.gov/drug-information/drug-scheduling. Schedule I substances also have a high potential for abuse and dependance. The difference is that Schedule I substances have no recognized medical use; Schedule II substances such as opioids do.

prescriptions written per prescriber, method of payment used, and other factors relevant to changes in the volume of its clients' opioid sales.

87. The inputs necessary for a Registrant to identify suspicious orders that merit reporting are the same inputs that Defendants Publicis and ZS collect, analyze, and synthesize in order to define and target the marketing campaigns for its clients. Upon information and belief, the same information utilized and analyzed by Publicis and ZS and presented to their clients for purposes of devising and optimizing opioid sales and marketing efforts should have led to obligations by Publicis' and ZS' clients – as registrants under the CSA - to report suspicious activity to the DEA.

88. Many states, including Illinois, enacted similar state laws, rules and regulations in order to regulate the manufacture, marketing, distribution and dispensing of controlled substances and provide oversight over this unique industry.[39]

89. In order to keep these dangerous and addictive drugs out of the wrong hands, this closed-system of state and federal authority imposes specific duties upon Registrants to monitor, identify, halt and, perhaps most importantly, report suspicious orders of controlled substances. 21 C.F.R. § 1301.74; *Masters Pharm., Inc. v. Drug Enf't Admin*., 861 F.3d 206 (D.C. Cir. 2017).

C. Publicis: "The Power of One"

90. Defendant Publicis Health is an advertising and consulting company that services pharmaceutical manufacturers. Publicis Health is a division of the French multi-national advertising and communications conglomerate Publicis Groupe, S.A. ("Publicis"). Annual revenues exceed $9 billion.

[39] *See* 720 ILCS 570/401 *et seq*.

91. Today, Publicis operates numerous subsidiaries focusing on subsets of the advertising industry. Publicis Health is the conglomerate's division that specializes in work for healthcare and pharmaceutical companies. Within Publicis Health, there at least fifteen "agency brands" – subsidiaries, essentially, operating under their own brand names. Each provides specialized advertising and communications strategies to Publicis' pharmaceutical clients. Razorfish Health, Publicis Health Media, Digitas Health, Rosetta, and Verilogue are some examples.[40]

92. Each brand specializes in a specific niche within the overall suite of sales and marketing services offered by Publicis Health. Razorfish pioneered and specializes in digital marketing; Digitas specializes in interactive marketing; Publicis Health Media's wheelhouse has been creative and media marketing. Verilogue's niche is providing audio recordings of interactions between patients and doctors that may be mined for insights on how to sell more drugs. Routinely, a Publicis client would engage with more than one of its subsidiaries in tandem and as part of an overall client relationship with Publicis.[41]

93. Until 2019, Publicis also owned Publicis Touchpoint Solutions, which provided contract sales organization ("CSO") services to pharmaceutical manufacturer clients.[42] Pharmaceutical companies routinely seek to optimize their salesforces to maximize profitability. As such, the typical pharmaceutical company does not maintain under-utilized salesforces, or salesforces larger than necessary to maximize revenue on the company's current product offerings.

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[40] *See* https://publicishealth.com/companies.

[41] For example, upon information and belief, Purdue used Publicis Health Media and Razorfish during the same year, and paid separate invoices to each agency, despite their joint ownership.

[42] On January 31, 2019, Publicis Healthcare Solutions, formerly known as Publicis Touchpoint Solutions, was sold by Publicis Groupe to Altamont Capital Partners. *See* "Altamont Capital Partners Acquires Publicis Healthcare Solutions," January 31, 2019, *available at*: https://www.prnewswire.com/news-releases/altamont-capital-partners-acquires-publicis-healthcare-solutions300787750.html#:~:text=Altamont%20Capital%20Partners%20Acquires%20Publicis%20Healthcare%20Solutions

The result, oftentimes, is that a pharmaceutical company hoping to launch a new product will not have the resources in-house to adequately push a new product launch.

94. Publicis Touchpoint Solutions solved these problems for clients by offering contract salesforces to augment the number of sales representatives a manufacturer can deploy in order to maximize the success of a product launch. Or, in many cases, Publicis would employ and control the entire sales force for a given drug, on a contract basis, for drug manufacturers that wish to outsource the entirety of their sales and marketing efforts.[43] As will be seen, Publicis Touchpoint Solutions provided sales representatives to numerous opioid manufacturers for numerous opioid products at different stages of the product life cycle.

95. These different divisions offering complementary services to clients function as a seamless whole. "'The Power of One' is Publicis Groupe's operating philosophy. Bringing together 80,000 employees across more than 110 countries and 56 agency brands, we deliver a seamless and modular experience in the relentless service of our clients," Publicis says.[44] That seamless and modular experience is "free from silos," with "unified P&L's" and no operational barriers between Publicis' brands.[45]

96. "The Power of One" is more than a marketing pablum. It governs the operations of the parent organization and how it exerts control over its numerous agencies. This control can at times lack subtlety. "Publicis Groupe executives gathered a few months ago to debate which agency would service a new piece of business won by the holding company's centralized Power of One team, which is composed of talent from its various shops. According to a person at the

[43] While the new product launch is a classic use case for a CSO, it is not their only use. A drug manufacturer may also choose to utilize a CSO at other stages of the product life cycle, for instance as loss of exclusivity approaches and a manufacturer wishes to re-deploy its internal sales force to focus on newer drugs or those about to be launched.
[44] *See* https://publicishealth.com/companies.
[45] *See* https://www.publicisgroupe.com/en/the-groupe/about-publicis-groupe

meeting – a former creative from a Publicis agency – a suggestion was made for the assignment to be handled out of Saatchi & Saatchi New York. According to that creative, one of Publicis' CEO-Chairman Arthur Sadoun's 'main people' responded: 'Don't put that there; [Saatchi] won't be here next year.'"[46]

97. By October of 2021, Publicis had risen to become the largest advertising conglomerate in the world, with a market capitalization of a little more than $16 billion.[47]

D. What Publicis Does: Marketing and Consulting

98. Traditionally, the advertising industry organized itself based on the "agency model," with advertising agencies performing both creative and advertising placement services. At the top of the pyramid was the "agency of record," or "AOR." The AOR is the advertising agency appointed by the client to coordinate the purchase of media time and space for the placement of client advertisements. While any given client may choose to employ multiple advertising agencies to assist with specific projects, the AOR sits atop those other agencies performing project work and directs the placement of project work performed by other agencies for the client. Typically, the AOR will receive payment from an agency performing project work for the client for its placement.[48] Given its control over the placement of client content – in effect, a monopoly on the client marketing distribution channel – the AOR was in a position to influence the conduct of other contracting agencies performing discrete projects for the client, should the client choose to utilize different agencies for different marketing functions (digital vs. print media, for example).

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[46] Lindsay Rittenhouse, "Uncertainty Over Future Direction of Publicis Triggers Employee Unrest – And Talent Exodus," *Ad Age*, January 16, 2020, *available at*: https://adage.com/article/agency-news/uncertainty-over-future-direction-publicis-triggers-employee-unrest-and-talent-exodus/2226346

[47] Gideon Spanier, "Publicis overtakes rivals to be world's most valuable agency group," *PR Week*, October 27, 2021, *available at*: *https://www.prweek.com/article/1731568/publicis-overtakes-rivals-worlds-valuable-agency-group*

[48] *See* Definition of Agency of Record, *allBusiness*, *available at*: https*://www.allbusiness.com/barrons_dictionary/dictionary-agency-of-record-4962111-1.html*

99. Publicis' various divisions performed multiple roles for various opioid manufacturers, including AOR roles on numerous campaigns as well as project work under the aegis of other AORs. Publicis' Rosetta, for example, [redacted] Publicis' Saatchi & Saatchi Healthcare [redacted].

100. The traditional AOR model has evolved significantly over the years as a result of consolidation within the industry, as well as competition from without. As the marketing industry has consolidated into the Big Four, it has transformed its product offerings in response to competition from consulting firms. The result is that Publicis has outgrown its heritage and is now far more than an advertising agency. It has transformed into an offeror of strategy and consulting services in addition to traditional agency work.[50]

101. In response to competition from outside the traditional agencies, coupled with the expansion of traditional advertising channels to encompass new technologies, the rise of digital marketing, the erosion of traditional print mediums, and other market dynamics, the Big Four agencies have evolved in recent years beyond the traditional AOR hierarchy to offer services to their clients in more nuanced and flexible ways, and to pair traditional product offerings with newer services.

E. A Consulgency

102. Publicis is no exception; indeed, it is an exemplar of these industry trends.

103. These days, Publicis is not just a content creator and placement agent; it is also a consultant. Indeed, the evolution of management consulting and advertising (and *particularly* pharmaceutical advertising) has created a market reality in which there is substantial overlap in

[49] Transcript of Amanda Stephens Hogan Deposition dated January 25, 2019, Pg. 414:3-8,

[50] For example, Publicis Sapient's Strategy & Consulting Practice Group describes its approach, "Our strategy and consulting teams work seamlessly with our experience and engineering teams to ensure we develop the most high-impact strategies to drive effective digital business transformation."

the product offerings of global advertising agencies like Publicis and global management consultants like McKinsey & Company, Inc. Just as McKinsey's traditional management consulting business has evolved to encompass various operational roles performed for clients, including sales and marketing design and implementation, the traditional advertisers have similarly evolved.

104. Publicis, for example, evolved to offer strategy consulting services and perform implementation work in addition to merely proposing advertising campaigns. By 2018, Publicis' investor presentation emphasized this shift, declaring that "We have the organization to *shift* from a **communications** partner to a **transformation** partner."[51] The goal of any Publicis client relationship is to "be our clients' indispensable partner in their transformation."[52]

105. This is part of a broader shift in the overall consulting and marketing industries. "Traditionally, marketing agencies spoke to the Chief Marketing Officer and implemented communication strategy, while consultants spoke with the CEO and devised the general strategy – with marketing communications being the tail of it. In an effort to compete, agencies have started to develop consulting skills, creating 'consulgencies.'"[53] As an example, Publicis' Publicis Sapient division was ranked in 2019 as the premier leader in providing "digital transformation" services, besting traditional consultants Accenture, Ernst & Young, PwC, and McKinsey.[54] According to the rankings analysis, these digital transformation leaders "blend strategy and execution chops and couple them with the soft skills for inspiring leadership and training teams," and identified Publicis as "the top consultancy on the customer experience front" and "an especially strong partner where

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[51] Publicis Groupe Investor Day Presentation dated March 20, 2018, *available at*: http://documents.publicisgroupe.com/events/2018-03-investor-day-intro.pdf (emphasis in original).
[52] *Id.*
[53] "Agencies, consulting firms, and the future of marketing," *Rewire Mag*, *available at*: https://rewire.ie.edu/agency-vs-consulting-firms-future-marketing/
[54] https://www.consulting.us/news/1991/publicis-sapient-named-a-leader-in-digital-transformation

the transformation emphasis is on creating world-class digital customer and employee experiences."[55]

106. One marketing executive, upon his company being acquired by a large consulting firm, explained, "we see the next decade as belonging to what we call 'consulgencies' – offerings at the cusp of what consultancies do and agencies do – bringing the best of both worlds together."[56] One benefit of this hybrid model is greater access to client information than a traditional agency model would entail. "I think consultancies are allowed more to look at the business side of things than agencies. Clients are not willing to share confidential information with us," explained one marketing professional.[57]

107. A natural outcome of this convergence between the management consulting and advertising industries has been partnerships between incumbent management consultants and incumbent agencies as both find themselves competing for the same business in a new competitive landscape.

108. Publicis and McKinsey routinely partner on projects together for mutual clients.

109. "McKinsey & Company and Publicis Health work together to help clients develop agile approaches to winning launches," declaimed a pharmaceutical industry marketing

[55] "Publicis Sapient named leader in digital transformation," *Consulting.us*, March 21, 2019, *available at*: https://www.consulting.us/news/1991/publicis-sapient-named-a-leader-in-digital-transformation. Firms like Razorfish and Sapient were seen as competitors to McKinsey from the outset, as McKinsey was experiencing a wave of employee departures during the early 2000's. "It wasn't just dot-com startups that were alluring. A whole new class of consulting firm burst onto the scene, with hipper names – Razorfish, Scient, Viant, and Sapient – and sexier projects. The work they were doing seemed far more crucial than redrawing organizational charts. They were helping companies use the Internet to transform everything about the way they did business – from sourcing to distribution to how they treated and served their customers." Duff McDonald, *The Firm*, Pg. 265. Razorfish, Scient, and Sapient were eventually acquired by Publicis. (Viant, which was *not* scooped up by one of the Big 4, was instead acquired in 2002 by a company named Divine that liquidated in bankruptcy the following year.)

[56] "The deal that unlocks the value of our industry," *Marketing Magazine*, June 8, 2018, *available at*: https://marketingmagazine.com.my/arrival-of-the-consulgency/

[57] Shareen Pathak, "'We're giving the business away to consultants:': Agencies brace for new competition, *Digiday*, October 25, 2017, *available at*: https://digiday.com/marketing/giving-business-away-consultants-agencies-brace-new-competition/

publication.[58] In 2016, Janet Winkler, then a Group President at Publicis Health[59], and Brian Fox, a Senior Partner at McKinsey, co-authored the article "Five Inconvenient Truths That Can Make or Break a Product Launch" in industry trade publication PM360.

110. McKinsey and Publicis co-authored[60] the piece to highlight their joint expertise in pharmaceutical marketing. "Applying complementary tools and capabilities, [McKinsey and Publicis Health] deliver rapid, actionable analytics as well as change management and execution support to accelerate brand performance throughout the lifecycle," explained a note accompanying the article.

111. Purdue is one example, but Publicis and McKinsey had many other mutual opioid manufacturer clients. They worked for these clients contemporaneously and for years while the opioid epidemic grew to its present scourge.

F. Publicis and Purdue: Selling the Sackler Strategy

112. As explained above, in the wake of Purdue's 2007 guilty plea with the Department of Justice and entry into to a 5-year Corporate Integrity Agreement with the Office of Inspector General for the United States Department of Health and Human Services, Purdue faced newly imposed constraints on its sales and marketing practices. As a result, the Sackler family desired to

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[58] Janet Winkler, Brian Fox, et. al. "Five Inconvenient Truths That Can Make or Break a Product Launch," PM360, November 23, 2016, *available* at: https://www.pm360online.com/five-inconvenient-truths-that-can-make-or-break-a-product-launch/

[59] In 2017, Winkler left her role as Group President of Publicis. The following year, she joined McKinsey & Company as a Senior Advisor.

[60] In addition to Winkler and Fox, "Gregory Graves, Associate Partner, McKinsey & Company; Catherine Mayone, EVP, General Manager, Publicis Health and Sapient Health; and Dan Tinkoff, Partner, McKinsey & Company, also contributed to this article." *See* https://www.pm360online.com/five-inconvenient-truths-that-can-make-or-break-a-product-launch/

Notably, the McKinsey authors – Fox, Graves, and Tinkoff – [redacted]

achieve distance from this "concentration of risk" by diversifying the family fortune away from Purdue, and by increasing OxyContin sales in the near term in order to achieve that distance.

113. Alongside McKinsey, Publicis was integral to the sales and marketing campaigns deployed to increase OxyContin sales notwithstanding the Corporate Integrity Agreement and in furtherance of the Sacklers' wishes.[61]

1. Hopelessly dependent on consultants; "Desperately seeking new growth."

114. Purdue was captured. After the 2007 guilty plea, the Sackler family wished to dispose of Purdue because it was concerned about both legal liability and reputational risk associated with owning the monoline opioid manufacturer. After 2007, the name of the game was profit maximization of a drug Purdue's owners knew had no long-term future.

115. The company, in other words, was a basket case: pursuing internally contradictory goals to maximize opioid sales because its previous efforts to maximize opioid sales had created an existential crisis for the company. Threading a needle like that is hard. Purdue needed others to tell it what to do in order to achieve its owners' mandate.

116. By the end of 2013, Purdue was seeking any opportunity to maintain growth it could identify. Publicis noted that Purdue's Board (meaning the Sackler family) was "always looming," and the pressure was always to increase sales. One risk Publicis identified was the risk that the Sacklers would fire the CEO at that time, John Stewart.

117. Publicis summed up its outlook for its client, "PURDUE in 2014: Desperately seeking new growth."

[61] To emphasize the disregard with which the CIA was met, Dr. Richard Sackler has testified, incredibly, that he has never read the agreement, despite his years of continued service on Purdue's Board of Directors before, during, and after the CIA compliance period.

118. This is red meat to consultants. McKinsey & Company. ZS Associates. Publicis. These happy warriors[62] serviced Purdue after the company's executives pleaded guilty in 2007, and with full knowledge of that guilt.[63] All worked for Purdue on an ongoing basis right up until Purdue stopped marketing OxyContin in 2018. And they worked *together*. They teamed up to service a client so dependent on their offerings that it could no longer function without their ongoing assistance.

119. Indeed, the consultants banded together to achieve their own goals with respect to mutual clients. "McKinsey & Company and Publicis Health work together to help clients develop agile approaches to winning launches. Applying *complementary* tools and capabilities, they deliver rapid, actionable analytics as well as change management and execution support to accelerate brand performance."[64]

120. As will be seen, Publicis' complementary tools and capabilities were critical to McKinsey's *Project Turbocharge*, which was adopted by Purdue and implemented by all three (and ZS) in late 2013 and thereafter. Crucially, Defendants – alongside McKinsey – worked with their clients to *implement* the advice and recommendations they provided after the client agreed to do so.

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[62] Consultants love martial metaphors. *See "*Publicis 2020: Sprint to the Future," Publicis Groupe, March 20, 2018, *available at:* https://www.publicisgroupe.com/en/news/press-releases/publicis-2020-sprint-to-the-future-en-1 (Publicis helping clients to "reduce their costs and win the battle with new competition); *see also,* "A battle plan for telcos' digital attacker brands," McKinsey & Co., March 5, 2021, *available at*: https://www.mckinsey.com/industries/technology-media-and-telecommunications/our-insights/a-battle-plan-for-telcos-digital-attacker-brands;

[63] For example, an internal Publicis Client Service Team review document prepared in 2013 for the Purdue account began with a section entitled, "To know Purdue," which stated, "In 2007, John Brownlee U.S. Attorney charged that 'Purdue, under leadership of its top executives, continued to push a fraudulent marketing campaign… In the process scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less abusable and less addictive than other pain medications on the market."

[64] Janet Winkler and Brian Fox, "Five Inconvenient Truths That Can Make or Break a Product Launch," PM360, November 23, 2016, *available at*: https://www.pm360online.com/five-inconvenient-truths-that-can-make-or-break-a-product-launch/ (emphasis added).

2. Branded Marketing

121. Purdue was a monoline manufacturer of opioids. OxyContin (oxycodone), Hysinglia (hydrocodone), Targiniq (oxycodone/naloxone) and Butrans (buprenorphine) were Purdue's principal branded opioid products. Publicis worked on campaigns for all four. But OxyContin was the cash cow. As Publicis' Rosetta unit described it in 2014, "for 17 years Purdue has relied almost solely on the revenue from their $3b blockbuster opioid medication, OxyContin (~90% of Purdue's revenue)."

122. The Publicis-Purdue relationship began as early as April 2010, during the pendency of the 5-year Corporate Integrity Agreement to which Purdue was bound as a result of its 2007 guilty plea, when Rosetta Marketing Services LLC entered into a Master Services Agreement to work on OxyContin and other Purdue opioids.[65] The Purdue relationship lasted as late as 2019.

123. As one industry trade journal described the relationship, "Rosetta's unique role lies in developing personalized marketing program built on consumer insights, as in the agency's integrated campaigns for… Purdue's pain drug OxyContin and pain patch Butrans"[66]

i. OxyContin

124. From the outset of the Purdue relationship in 2010, Publicis entities, beginning with Rosetta, were Covered Persons[67] pursuant to the Corporate Integrity Agreement Purdue was then bound by, and which remained in effect until May 2013.

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[65] Publicis acquired Rosetta in May of the following year for $575 million. *See* Eric Pfanner, "Publicis to Acquire Rosetta for $575 Million," *New York Times*, May 17, 2011, *available at*: https://www.nytimes.com/2011/05/18/technology/18iht-publicis18.html

[66] Marc Iskowitz, "100 Agencies: Rosetta – Acquisition by Publicis, integration activities lead to flat year for agency," *Medical Marketing and Media*, July 1, 2012, *available at*: https://www.mmm-online.com/home/channel/features/100-agencies-rosetta/

[67] The relevant language in the Corporate Integrity Agreement provides: "'Covered Persons' includes . . . all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions . . . on behalf of Purdue."

(a) Project Turbocharge a/k/a Evolve to Excellence a/k/a E2E

125. Within a few *months* of its expiration, and with the CIA now out of the way, McKinsey proposed, and Purdue adopted, *Project Turbocharge*, a sweeping effort to revitalize OxyContin sales by overhauling and empowering Purdue's sales force to deliver in a precision-targeted way new messaging regarding OxyContin. Purdue adopted McKinsey's recommendations, coordinated with McKinsey to implement the recommendations, and immediately involved Rosetta in doing so. As a sign of the transformative nature of the undertaking, the project was unveiled as the theme of Purdue's 2014 national sales campaign.

126. On Saturday, September 28, 2013, [redacted] he explained.[68] [redacted]

127. [redacted].[70] [redacted]

[68] PPLPC018000873870.
[69] PPLPC018000873870. "ADF" is an acronym for "abuse deterrent formulation," i.e., the reformulated OxyContin that was crush-resistant. ADF is addressed further in this Complaint, below.
[70] PPLPC018000873870.

[redacted].[71]

128. From the outset, Rosetta was an integral partner in shaping what McKinsey's program would become. By the end of the first month of *Project Turbocharge*, Rosetta was working to assemble, ratify, and finalize informational streams from other consultants regarding targeting healthcare providers with new OxyContin messaging. [redacted] The additional work included [redacted]

129. Internally, Rosetta envisioned itself as perhaps playing an *even more* central role in McKinsey's *Project Turbocharge* at Purdue than it actually did. Rosetta described itself in an internal presentation as the "strategic backbone" of Purdue's marketing efforts, including *Evolve to Excellence*, which Rosetta identified as one of the definitive characteristics for "success" at Purdue in 2014. [74]

130. Whether backbone or limb, Rosetta was present at the creation.[75] The following sections describe certain components of Rosetta's work on *Evolve to Excellence* (or *E2E*, f/k/a

[71] PPLPC018000873870.
[72] PPLPC018000885202
[73] PPLPC018000885202
[74] McKinsey's name, "Project Turbocharge" was seen as perhaps too crass or off-tone by Purdue. At a minimum, it was not "permanently appropriate." CEO John Stewart wrote to McKinsey partners Rob Rosiello and Arnab Ghatak on August 15, 2013: "Paolo Costa was especially engaged in the discussion and he (among others) will be a champion for our moving forward with a comprehensive 'turbocharge' process – *though we do need to find a better and more permanently appropriate name*." (emphasis added). They settled on the decidedly more anodyne "*Evolve to Excellence,*" (or "*E2E*").
[75] *See* Dean Acheson, *Present at the Creation: My Years in the State Department*, W.W. Norton, (1969).

Project Turbocharge). The conduct described is not exhaustive of Rosetta's (or Publicis') work in conjunction with McKinsey and for Purdue relating to *E2E* and adjacent projects. It is merely illustrative.

(b) Titration and Length of Therapy

131. If you sell drugs to people, there are two ways to sell more drugs. One is to start selling the drug to someone who wasn't using it before (or, to use the lingo, a "new patient start"). The other way is to sell more of it to the people already using it. Titration and Length of Therapy ("LoT") efforts are directed at the latter opportunity. Stronger pills made more money; the higher the dosage strength for any individual OxyContin prescription, the greater the profitability for Purdue. Publicis went to great lengths to quantify the money to be made from increasing the length of therapy. According to their calculations, an increase of 1% in average LoT for yearly unique patients represents $20 million in additional revenue to Purdue:

From: Ben Meck <ben.meck@rosetta.com>
Date: Tuesday, August 19, 2014 at 11:09 PM
To: John Dwyer <john.dwyer@rosetta.com>
Subject: RE: ERO/OxyContin slide deck

Okay, I can adjust based off this.

- Which do you like better? Since you might be presenting
  - Every increase of 1% for average LoT for yearly unique patients (from 125.3 days on therapy to 126.6 days on therapy) is $20M potential
  - Every increase of 1 day for average LoT for yearly unique patients (from 125.3 days on therapy to 126.3 days on therapy) is $16M potential
- Money point that I can include on the slide
  - Increasing average LoT by 2.5% for yearly unique patients (from 125.3 to 128.4 days on therapy) is $50 million potential

Ben Meck
Manager | Analytics & Optimization
Office +1 347.332.7655 Mobile +1 917.754.0041
99 Hudson Street, 11th Floor, New York, NY 10013, USA
Rosetta.com
Rosetta. Unlock and Activate™ Human Behavior.

132. Of course, higher dosage strength and increased lengths of therapy also contribute to opioid dependency, addiction and abuse. But Publicis was there to focus on selling higher strength dosages of OxyContin, and ROI was what was most important.

133. From 2012 through 2014, Publicis worked on numerous projects to design or refresh marketing campaigns to drive higher dose prescribing, for longer periods of time. In August of 2012, Publicis explained, "A strategic driver for [OxyContin] in 2013 is to drive appropriate titration and length of therapy with continuing patients. In an effort to add more emphasis to the importance of titrating to adequate analgesia… the brand team would like to create a 'campaign' to raise awareness."

134. Remarkably, Publicis created two *separate* marketing campaigns: one internal, for the Purdue sales representatives to understand how important titration and length of therapy is to *Purdue* (i.e., how the messaging effects profits), and a separate one designed to deliver the broader message to prescribers.

135. In September 2013, Publicis was brought in to "refresh" the already existing *Individualize the Dose* titration campaign. The campaign had its origins around four years prior when, on October 26, 2009, McKinsey advised the Sacklers and the Purdue board that Purdue should train its sales representatives to "emphasiz[e] the broad range of doses," which would have the intended effect of increasing the sales of the highest (and most profitable) doses of OxyContin. McKinsey and Purdue subsequently implemented the campaign, and Publicis was brought in to do the "refresh" of the campaign in light of "an emerging market dynamic": the decline in "mean patient dose" of OxyContin.

136. In other words, patients were buying less drugs. Publicis was brought in to reverse the decline; to "shift" the "trend":[76]

[76] *See* 2013-09-03 Rosetta Creative Brief, cited in the Massachusetts Attorney General Complaint, Paragraph 57.

137. With respect to length of therapy, Publicis offered up a blunt instrument: coupons. In April of 2013, Publicis deployed an email marketing campaign, which sent out "Savings Cards" for OxyContin that could be downloaded. These coupons were known to be an effective method of encouraging patients to continue taking OxyContin for longer than they typically would otherwise.

138. The work continued into 2014 as *E2E* was being implemented, by which time Publicis was asking probing questions like, "Does a titration step lead to longer LoT?" "Does 1 titration step correlate with a higher likelihood of a 2nd titration step? And a 2nd to a 3rd, and so on?"

139. In 2017, Publicis employees discussing titration messaging knew the score. As one put it, "We know discontinuation is usually an irrelevant subject matter (the persistent mindset is, once on an ERO [Extended-Release Opioid], the only way is up."

140. Higher doses of opioids taken for longer periods carry greater risk. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. The Centers for

Disease Control and Prevention also recognize that higher doses of opioids tend to increase overdose risks relative to any potential patient benefit.[77]

141. Claims that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose, are not only deceptive and misleading, they are deadly. These claims were particularly important to promotional efforts, however, because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Marketers needed to generate a comfort level among doctors to ensure the doctors maintained patients on opioids even as the high doses became necessary.

142. Publicis was ever vigilant in its protection of the titration messaging. In a June 2014 internal "Brand Overview" presentation regarding OxyContin, a Publicis employee struck out language in a draft version referring to utilizing the "lowest possible dose" because that language was contrary to the titration and length of therapy goals for the brand.

143. The vigilance paid dividends; the titration messaging worked. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than sixty milligrams per day, which converts to the ninety MED that the CDC guideline urges prescribers to "avoid" or "carefully justify."[78]

(c) Targeting Patients; Targeting Prescribers

144. In order to aid prescribers and to deliver the titration message, Rosetta sought to differentiate and segment patients into different "types," so that physicians might familiarize themselves with instances in which titration is appropriate. In June 2014, in furtherance of the *E2E*

[77] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1
[78] CDC Guideline at 16.

initiative, Rosetta was hired to refresh two and create a third "patient profile," which could be left behind in brochure form in healthcare providers' offices.

145. These profiles were meant to personalize OxyContin patients in the eyes of the prescriber and described the instances in which an OxyContin patient's dosage should be changed. "Maggie" is 43 years old with "significant" lower back pain. After falling at home, she begins a 40mg OxyContin twice daily regimen, and is then titrated up to a 60mg tablet twice daily before she "reports that her pain is properly managed." "Carol" is 51 years old and has osteoarthritis in her left hip. She starts at a 15mg dose and is titrated up to 20mg dose, "with better relief of pain symptoms." "James" is 40 and his osteoarthritis is in his knee. He starts at a 10mg OxyContin dose, then is doubled titrated to 15mg. After reporting that "his pain is still not well managed," James is titrated up again to a 20mg dosage, at which point he experiences "good response to his arthritic pain."

146. Notably, in none of these patient "vignettes," as Rosetta called them, was a patient ever titrated *down*. With EROs like OxyContin, the goal of titration was always ever skyward. These patient vignettes were to be included alongside information about obtaining "savings cards" – coupons – in order to get a discount on your OxyContin prescription. The savings cards were offered because Publicis knew from experience that their use correlated with longer average length of therapy for the patients that used the coupons.

147. Another patient group that Rosetta targeted were individuals already prescribed short-acting opioid medications. The goal was to transition these patients to an extended-release formulation for long-term management of their pain. A longer length of therapy on an ERO like OxyContin is more profitable than sales of short acting opioids.

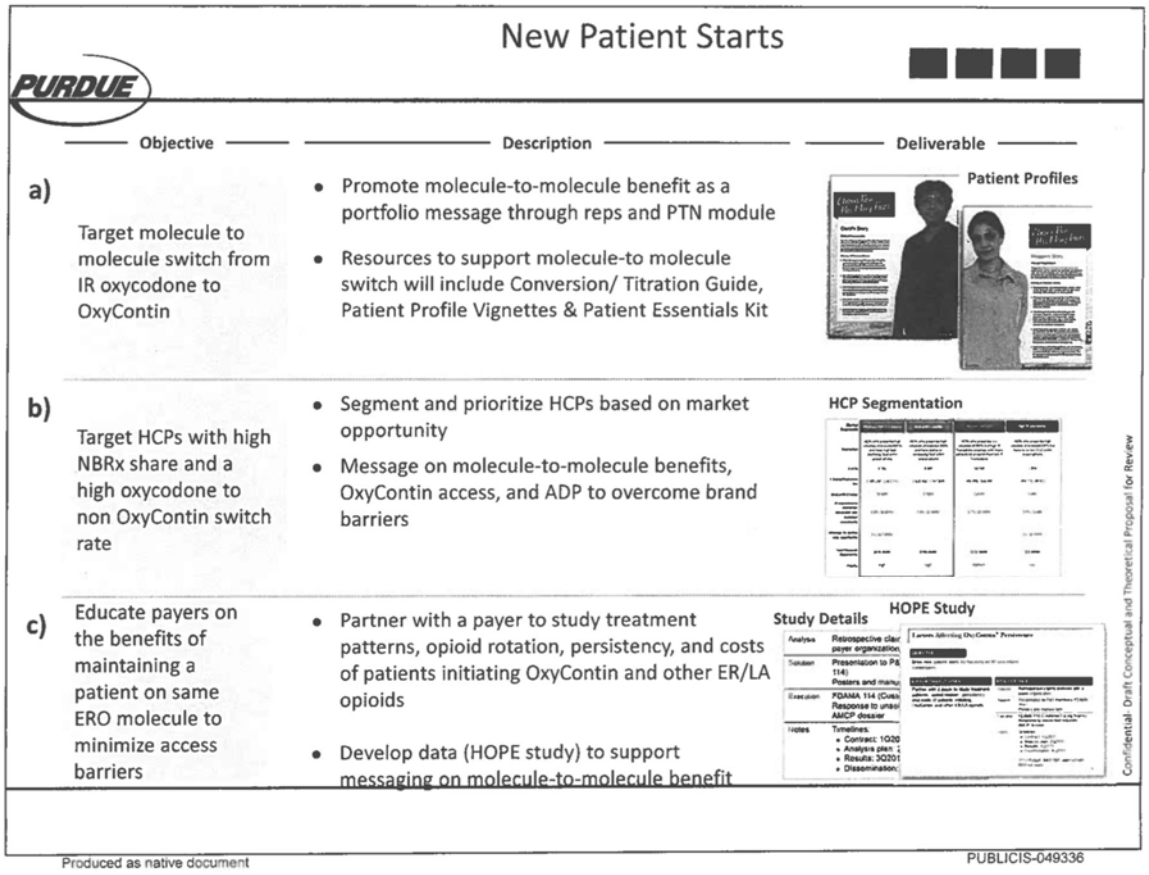
148. As Rosetta segmented and targeted patient types, so too did it segment and target certain prescribers. It did so in order to deliver tailored messaging to targeted individuals in order to maximize the goal, to [redacted]

149. As mentioned above, from the outset of *E2E*, Rosetta was working on identifying target lists of OxyContin prescribers, [redacted][80] Rosetta's targeting efforts were organized by segmenting OxyContin prescribers into deciles by volume of prescriptions written.

150. Once these target lists were compiled, the purpose was to concentrate marketing efforts on the highest decile prescribers, i.e., those doctors who were already prescribing OxyContin and who, upon information and belief, had previously been subjected to Purdue's tainted marketing efforts *prior* to the 2007 guilty plea.

151. At the same time, Publicis also focused marketing efforts on *new* prescribers who were prescribing more OxyContin than their peers. This separate market segment of "new to brand prescribers" (or "NBRx") could be plumbed for additional growth. Thus, Publicis advised sending sales representatives to both "high decile prescribers" and "High-decile NBRx HCPS" up to three times a month. These efforts were part of an overall initiative to generate "new patient starts" (which is one way to increase sales, the other being Titration and Length of therapy, described above), as set forth in an "OxyContin 2015 Tactical Planning" presentation prepared by Rosetta:

[79] PPLPC018000873870.
[80] PPLPC018000885202.



152. Rosetta identified these physician targeting efforts to sell more OxyContin, which could result in more than $1 billion of additional revenue for Purdue.

153. The targeting was not limited to segmenting physicians into deciles by volume of OxyContin prescriptions written. It also identified different physician profiles. Two patient profiles in particular were identified for targeting. The "motivated believer" was "convinced that opioid medication is essential to treatment of the chronic pain patient" and recognized OxyContin as "the leading FDA-recognized Opioid with Abused Deterrent Properties." A "brand loyalist" was a prescriber that would remain an OxyContin prescriber despite growing concern within the medical profession regarding its abuse liability.

154. One difficult physician segment type is the "no-see." Some physicians simply do not want to see sales representatives and will not meet with them in person. Obviously, this creates

an impediment to access that pharmaceutical manufacturers seek to surmount. If you cannot communicate to a physician, it is difficult to influence that individual's prescribing patterns. Rosetta offered solutions.

155. Of course, there are other channels that can be used, such as email marketing campaigns, and this Rosetta did. But there are other ways to gain access. For instance, Publicis suggested that a list of all "no-see" prescribers who worked at "integrated delivery networks" be compiled: "We should target anyone on the IDN Lists… regardless of decile." Rosetta and Purdue then set up a call center where these prescribers who did not wish to meet with sales representatives would receive phone calls instead.

156. Another response to barriers to physician access is to go around them, to talk to someone else at the doctor's office instead. Rosetta designed strategies to target physician assistants and nurse practitioners instead of the physicians themselves. Like the physician profiles it created, Rosetta also segmented the physician assistants and nurses into "attitudinal and behavioral profiles," the better with which to target OxyContin messaging, such as "dose titration opportunities." In 2015, Rosetta proclaimed that these efforts to target nurses and physician assistants could yield an additional 14,500 OxyContin prescriptions in the first year of implementation.

157. Two years later, Publicis' efforts at targeting nurses and physician assistants continued, with a Publicis employee noting the particular importance of this market segment for OxyContin. In a September 27, 2016, email, she noted, "NP/Pas are a growing provider segment and help offset the decline from PCPs."

158. Publicis also saw their work on targeting nurses and physician assistants as a cross-selling opportunity. In 2016, Rosetta suggested Purdue hire Rosetta's affiliate, Publicis Touchpoint

Solutions, to deploy clinical nurse educators "trained on the Purdue sales force platform" to help these nurses and PA's "understand and implement" OxyContin treatment plans and "overcome behavioral obstacles that may interfere with patient adherence."[81]

159. As a part of the overall implementation of *E2E*, Rosetta was involved not only in delivering the marketing messages that Purdue would then deliver to healthcare providers. Rosetta remained deeply involved in the actual rollout of these marketing messages. In July of 2015, three Rosetta employees on the Purdue account joined sales representatives in the field for ride-alongs to meet with targeted prescribers. These Rosetta employees observed in person the interactions between Purdue sales representative and target prescribers during which Rosetta's messaging was delivered. Rosetta was able to use the knowledge they gained from observing prescribers' reactions to their messaging, which further refined their approach and maximized the effectiveness of the marketing outreach.

160. These field trips served the overarching goal, as Purdue's Ron Cadet explained, to [redacted][82]

(d) Non-indicated Uses

161. Publicis introduced a search engine marketing "Conditions Campaign" for OxyContin as early as 2013 and continued these efforts throughout the implementation of *E2E*. The campaign was designed to drive prescribers conducting web searches about certain medical conditions – lower back pain, for instance – to Purdue's website. "The Campaigns pertaining to Conditions were the most successful out of last year's [search engine marketing] strategy and

[81] Consistent with the "Power of One" approach described supra., this was not the first time Publicis cross-sold other Publicis divisions into the Purdue account. In 2015, Razorfish advised Purdue to hire Verilogue without going through a competitive bidding process. This cross-selling initiative – a fine example of the "Power of One" in action – resulted in Verilogue's analysis of patient-provider conversations being used to devise to tactics to increase sales volumes of Purdue's opioids. Verilogue's was used in furtherance of targeting and messaging goals of *E2E*, and its work was part of the overall efforts to [redacted] PPLPC018000873870.

[82] PPLPC018000873870.

resulted in 25,548 Clicks, driving the most visits to PurdueHCP site," Publicis explained in a June 2014 presentation.

162. The Conditions that Publicis targeted included low back pain, cancer pain, and osteoarthritis pain. OxyContin is only approved, or indicated, to treat certain conditions, and is not approved to be marketed for a non-indicated use.

163. Publicis proposed to expand the Conditions campaign to target multiple sclerosis, trigeminal neuralgia, and spinal cord injury, but the proposal "raised some red flags." John Dwyer explained in an internal Publicis email, "there are search words that are disease states OxyContin is not indicated for. And by having it in a document associated with OxyContin even for internal review can put [Purdue] in a liability risk." Accordingly, Publicis altered the text of the advertisements that would appear when a given disease state was searched for in order to delete reference to that disease state. (The ads still appeared when prescribers searched for the non-indicated Conditions, the text of the ad merely referred to "that" condition, instead of a specific reference to multiple sclerosis, low back pain, or the like.)

ii. Purdue's other brands: Butrans, Hysinglia, *et. al.*

164. While OxyContin accounted for the lion's share of Purdue's revenue, the monoline manufacturer sold other flavors of opioids. By the end of 2016, Publicis had won the agency of record position for the rest of the Purdue's brands as well.

165. In a 2014 presentation, [redacted][83]

[83] PPLPC012000477940

Publicis worked on Purdue's Butrans, Intermezzo, Targiniq, and Hysinglia brands in addition to OxyContin.

166. The same year, John Dwyer met with Purdue's Peter Justaston to discuss "Agency consolidation," and what Publicis "would need to do" to win the single Agency spot. Dwyer assured Purdue that Publicis was "up to the challenge" of being the sole Agency for all of Purdue's products. It was a goal Publicis pursued doggedly.

167. "For the last 4 years, every year as we do the forecast for the new year, I've put 'Butrans AOR business' in there under whitespace, which is where we put areas where we think we can grow," John Dwyer said to his team at Publicis in April 2016. That year, Publicis achieved Dwyer's goal, with Purdue deciding to shift some work it previously assigned to competitor agencies to Publicis' Razorfish.

168. Dwyer sent a congratulatory email on April 4, 2016, to the Publicis team about Publicis' winning additional business from Purdue, and explained that their success on the OxyContin account is what drove the decision for Purdue to award Publicis' Razorfish additional work:

> … when the client told us that he was going to move the rest of the Butrans business over to Razorfish Health, the reason he said he was doing it was because he wanted up to replicate exactly everything we did last year [2015] on OxyContin. The creative campaign refresh, the vis[ual] aid that far outshone the Butrans and Hysinglia ones which were done by another agency, the strategic planning we brought them for the new competitors who are coming, and the overall revitalization of the brand… He said, "We want more like that. We want you to do the exact same thing this year, but now with Butrans.

169. The following month, Razorfish was awarded the Hysinglia account as well. Publicis' Karl Tiedemann noted in an email the "amazing relationship" developing between Purdue and Publicis, and quoted a Purdue employee as stating that the Hysinglia account was "the final piece and **we now own Purdue."** (emphasis added).

iii. Selling red herring: ADF

170. One way to keep selling opioids once widespread abuse and dependence has gripped the patient population that uses them is to introduce a new version of the drug that can be sold as "abuse deterrent." The opioid manufacturers did just that, with Purdue leading the way. Publicis was there at every step of the way to define the message and deliver it to crucial audiences: prescribers, patients, and regulators.

171. Purdue's "[abuse deterrent formulation] does not prevent abuse via swallowing," Publicis stated in a June 2014 confidential internal memorandum.

172. "As long as a drug is addictive, can be abused by swallowing higher doses, and ways to defeat the [abuse deterrent formulation] are online," no drug would ever meet the FDA's standard for "reduced abuse, misuse, and/or diversion in the community,"

explained former Publicis partner Ted Whitby in a June 15, 2017, email to his former colleagues at Publicis.

173. In other words, the new formulations didn't prevent abuse. They were red herrings, a distraction that an opioid manufacturer could point to in order to mollify regulators and other interested parties, while knowingly not addressing the underlying abuse liabilities of their products. Publicis knew this good and well, but never mind that. ADF was a message to deliver.

174. And Publicis was eager to spread the word. In July 2014 (*one month* after the internal Publicis memorandum discussing the ineffectiveness of the abuse-deterrent formulation), Publicis prepared the following language as a "value proposition" that sales representatives could recite to doctors: "OxyContin is the only opioid that addresses the pain management needs of both patients (efficacy and dosing flexibility) and society (proven abuse deterrent properties)."

175. This work was part of an ongoing project by Rosetta to get the ADF message out to the world for Purdue. On March 31, 2014, as part of the overall *E2E* initiative, [redacted][85] [redacted][86]

[84] PPLP0033598595
[85] PPLP0033598595
[86] PPLP004128540

176. The work proved grim. Publicis knew that the ADF messaging they were crafting was misleading, but craft it they did, nonetheless. In May 2015, Publicis was working on creating marketing messaging on the topic of the crush-resistant formulation of OxyContin introduced in 2010. Publicis was looking for data to support the claim that the reformulation was effective in reducing opioid use disorder. They just couldn't find it. The message would have to be carefully crafted, because Publicis couldn't find evidence to support their message: that the reformulation reduced abuse rates. As one Publicis employee described it, **"Ugh…"**:

To: Bruce Rinderman[bruce.rinderman@razorfishhealth.com]
From: Christina Ceniza
Sent: Mon 5/4/2015 4:06:00 PM (UTC-04:00)
Subject: Re: Abuse rates

Ugh – no you're right. I was trying to figure out if maybe the % of OXC to overall illicit use of pain killers went down, but it didn't. Maybe we can set up some time with Linda to talk through possible angles since she did a lot of leg work on lit search? Even if we can't find the data, we can craft the message and tell the Brand team what we WANT to say and see if their Medical Services group can come up with anything to support it?

Christina Ceniza
Director | Account

christina.ceniza@razorfishhealth.com
P 212.771.5157 M 646.469.9673

RAZORFISH | HEALTH
99 Hudson Street
New York, NY 10013, USA
razorfishhealth.com

From: Bruce Rinderman <bruce.rinderman@razorfishhealth.com>
Date: Monday, May 4, 2015 at 3:57 PM
To: Christina Ceniza <christina.ceniza@razorfishhealth.com>
Subject: Re: Abuse rates

Hi Christina,
Am I missing something or is there no story here? Please take a look at my markups (attached) and let's chat when you have a sec.
Thanks,
Bruce.

Bruce Rinderman
Creative Director

bruce.rinderman@razorfishhealth.com
P: +1 212 771-5455 M: +1 917 575-0834

iv. Responding to an External Threat: The Centers for Disease Control

177. In response to the growing crisis, in March 2016 the Centers for Disease Control and Prevention issued a *Guideline for Prescribing Opioids for Chronic Pain* (the "CDC Guidelines") in order to reduce the recognized overprescribing of opioids and the concomitant rise in opioid use disorder.

178. Within a month of their issuance, Publicis provided an assessment of the threats and opportunities that each of the twelve Guidelines posed. The "threat" was that the Guidelines would result in reduced OxyContin prescribing. The "opportunity" was that the Guidelines could be used to position Purdue's products to sell *more* of them by *using* the Guidelines.

179. In general, the Guidelines were seen as a threat as they recommended actions that ran directly counter to Purdue's marketing efforts. For instance, the Guidelines recommended that prescribers use the "lowest effective dosage" when prescribing opioids, which is anathema to the titration and length of therapy messaging that Publicis and Purdue had been articulating and delivering for years.

180. The Guidelines also called for a curtailment of prescriptions exceeding 90 morphine milligram equivalents per day. These high dose prescriptions accounted for nearly half of total OxyContin prescriptions and were each more profitable than their lower dosage equivalents. The Guidelines therefore risked to substantially erode OxyContin revenue. Purdue estimated that implementation of the Guidelines could cost in excess of twenty million dollars annually in lost sales in a single state.

3. Unbranded Marketing

181. It might be obvious, but "unbranded" opioid marketing does not promote any particular brand of opioid. Instead, unbranded marketing promotes opioids as a *class* of drugs worthy of ever increased prescription. Here, Publicis excelled in its work for Purdue.

182. If one thinks of the entire opioid market as a pie, each individual brand (as well as generic formulations) would comprise individual slices. Crucially, *even if* an individual product's market share does not change, that portion can grow in value if the *overall* market grows. The larger the pie, the larger the slice.

183. The long-term goal was to "make the whole pie bigger, not only for us, but for our competitors as well," a Purdue executive explained in a 2000 speech.[87]

i. Practical Tools to Advocate for yourself.

184. On January 22, 2012, Jennifer Grey, the actor known for co-starring in "Dirty Dancing," appeared as a "patient advocate" on a local television talk show in San Francisco to discuss "Partners Against Pain," a campaign with which she was affiliated. Noting the website's address for the audience, she explained, "it's called PartnersAgainstPain.com, and it's a really interesting educational program… It's a campaign that was meant to help people become advocates for themselves who are in chronic pain and because chronic pain is such an insidious syndrome."[88]

[87] Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, "Inside the opioid industry's marketing machine," *Washington Post*, December 6, 2019, *available at*: https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/

[88] Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, "Inside the opioid industry's marketing machine," *Washington Post*, December 6, 2019, *available at*: https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/

185. In 2019, Grey provided the *Washington Post* with the following statement regarding her prior affiliation with PAP[89]:

> When this unbranded [Purdue] Pharma campaign was brought to me in 2011, I was excited by the opportunity to help people who, like myself, suffered from chronic pain by giving them practical tools to advocate for themselves and manage their pain in a safe, responsible way. **I never suspected I was being used to potentially advance a darker agenda.** (emphasis added).

186. Rosetta and Purdue designed the PAP campaign together. [redacted] [redacted] [redacted].[90] They were the ones who "brought" the "unbranded [Purdue] Pharma campaign" to Grey.

187. From the outset, [redacted] [redacted].[91] [redacted] [redacted]

[89] Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, "Inside the opioid industry's marketing machine," *Washington Post*, December 6, 2019, *available at*: https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/
[90] PPLP003518651
[91] PPLP003518651

[redacted][92] [redacted]

[redacted].[93]

188. PAP was part of Purdue's broader efforts in the realm of "Patient Access," or, put differently, efforts to ensure that OxyContin was well-known and easily available to patients who desired to advocate for themselves and ask their doctor about OxyContin.[94] One method was to emphasize that pain is under-treated. [redacted]

[redacted][95]

189. Ms. Grey's later concern that she was "used to potentially advance some darker agenda" was prescient. There was more to it than "providing practical tools" to the local television audience so that they could "advocate" for themselves.

190. [redacted]

[redacted][96], [redacted]

[redacted][97] In furtherance of that goal, [redacted]

[92] PPLPC012000409258
[93] PPLPC017000301209
[94] *See* Dr. Anna Lembke, *Drug Dealer, M.D.*, pg. 58 (noting that the common pharmaceutical refrain to "Ask your doctor if drug X is right for you" – a form of patients advocating for themselves in conversations with healthcare providers – "can influence prescribing because doctors are eager to please their patients, and when a patient asks about a particular medication, a doctor may prescribe it over other comparable choices.").
[95] PPLPC017000541631
[96] PPLPC017000328575, at 328587. [redacted]
[97] PPLPC017000328575, at 328586.

[redacted]

(emphasis added).

191. In other words, Grey was hired to sell more drugs. Her work was just another line item in the marketing budget, and Rosetta and Purdue expected a return on the money spent for it.

192. Not content with Grey alone, Rosetta and Purdue enlisted Country Music Icon Naomi Judd as well. "Judd wants people to know the journey to appropriate pain management can begin with a visit to the recently updated Partners Against Pain website (www.PartnersAgainstPain.com)," proclaimed the press release.[99] [redacted]

[redacted][100]

193. Like Grey, Judd appeared in television spots as a "patient advocate".[101]

[98] PPLPC017000328575, at 328587.

[99] *See* https://ftper.newsusa.com/Pdfs/NaomiJudd.pdf

[100] PPLP003518651 at 3518686 (underlined emphasis in original; italicized emphasis added – [redacted].

[101] *See* https://www.youtube.com/watch?v=cUav8M9mep4

194. "From day to day, pain can limit your ability to work, your hobbies, even the simple joys of huggin' somebody you love," she explained.[102]

195. Five years later, in 2016, Publicis proposed to revamp the *Partners Against Pain* website in light of the fact that the website had been "named in lawsuits." Better to "start from scratch," Publicis proposed. Publicis instead pitched to Purdue its "Patient Support Program." The ultimate goal of the new campaign would be the same as the original *Partners Against Pain* campaign, "extending patients' length of therapy."

ii. Join the Team!

196. Razorfish Health was the agency of record for Purdue in connection with the launch of the now-defunct website TeamAgainstOpioidAbuse.com.[103] Purdue claimed the website was

[102] *See https://www.youtube.com/watch?v=cUav8M9mep4*
[103] Kevin McCaffrey, "Purdue debuts opioid-abuse resource," Medical Marketing and Media, August 17, 2015m, *available at*: https://www.mmm-online.com/home/channel/campaigns/purdue-debuts-opioid-abuse-resource/

"designed to help healthcare professionals and laypeople alike learn about different abuse-deterrent technologies and how they can help in the reduction of misuse and abuse of opioids."[104]

197. The unbranded website contained misleading information regarding the effectiveness of abuse-deterrent properties of certain opioid formulations, including Purdue's reformulated OxyContin and Hysinglia. At the time, only three abuse-deterrent formulations were available on the market (the third was Embeda, manufactured by Pfizer).[105] "The concept is that we're all part of a team," explained Dr. David Haddox, Purdue's Vice President of Health Policy.[106]

iii. The Meaning of the Message

198. There was a recursive nature to the marketing of opioids as companies evolved from *growing* the market for opioids to *responding* to the abuse and dependency issues that were the natural outgrowth of that initial boom in opioid sales. "Hello, my name is Mark Timney… We at Purdue are committed to doing everything we can to reverse this public health problem," read the script written by Rosetta for newly-installed Purdue CEO Mark Timney to read on a 60-second television ad prepared by Rosetta in 2014.

199. Initially, opioids were marketed primarily based on their efficacy (while disregarding their abuse liability). The PAP campaign was one facet of that effort. Once abuse became a concern, opioid marketers then sought to contextualize opioid addiction within a broader context of the individuals' right to manage their own pain as a part of their own interactions with

[104] "Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com," Purdue, Aug. 17, 2015, http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/.
[105] Kevin McCaffrey, "Purdue debuts opioid-abuse resource," Medical Marketing and Media, August 17, 2015m, *available at*: https://www.mmm-online.com/home/channel/campaigns/purdue-debuts-opioid-abuse-resource/
[106] *Id.*

the nation's healthcare system. The words Timney said on TV and the website TeamAgainstOpioidAbuse.com exemplify this later approach.

200. Melina Sherman, of the Institute for Public Knowledge at New York University, has written extensively regarding the evolving communications strategies used to market opioids. She explained, "[a]s its name indicates, the *Team Against Opioid Abuse* website is discursively constructed around the theme of abuse prevention – a decision that works strategically to shield the company [Purdue] from the negative press and attention being directed at its products."[107] But while the website did not specifically name brands of abuse-deterrent opioids, the website nonetheless operated to promote further use of Purdue's drugs. Of the three abuse-deterrent opioid products then on the market, Purdue manufactured two of them. As such, "the site also functioned as a marketing platform for those same drugs, which it framed as a solution to the problem of opioid addiction and abuse."[108]

201. It is no accident that Ms. Grey spoke about providing "practical tools" to *consumers* in order to allow them to "advocate" for themselves. These tactics, subtle and insidious as they are, are meant to increase overall opioid prescribing. "Pharmaceutical companies often mobilize education campaigns around a particular diagnosis in order to indirectly market the cure and as a mean of evading legal constraints that restrict the ways that companies advertise their drugs to consumers."[109]

202. Ms. Grey expressed concern about being used for a "darker agenda." It was simply to sell more drugs.

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[107] Melina Sherman, "How to Train Your Opioid Consumer," *Communication, Culture & Critique* Vol. 10 (2017), Pgs. 600-601.
[108] *Id.*
[109] Melina Sherman, "How to Train Your Opioid Consumer," *Communication, Culture & Critique* Vol. 10 (2017), Pg. 599 (*citing* Angell, M. (2004). *The truth about drug companies: How they deceive us and what to do about it*. New York, NY: Random House).

203. For example, the *Partners Against Pain* website that Ms. Grey promoted "groomed" potential opioid customers by offering assessment tools to website visitors – including "checklists and lists of questions used to guide patients through the process of obtaining medication from their doctors," as a means of educating the viewer.[110] The website also included a "Find a Doctor" tool, whereby viewers could search for pain management practitioners in their local area.

204. As the Rosetta ad that Purdue CEO Mark Timney read on TV emphasized, "Purdue is greatly expanding our ongoing efforts to help educate the public about prescription opioid abuse. We will be doubling our investment in 2015 to continue building awareness about the problem and better educating physicians, pharmacists, school health officials, insurers, and lawmakers about the risks of opioid abuse." TeamAgainstOpioidAbuse.com was one such educational effort.[111]

205. But "tools such as these go further than education: They also function as technologies of power that manage communication and information in a way that is normative and directional and, in so doing, guide visitors' behavior toward actions that benefit the company."[112]

206. Dr. Marcia Angell, former Editor in Chief of the *New England Journal of Medicine*, summed things up plainly:[113]

> No one should rely on a business for impartial evaluation of a product it sells. Yet the pharmaceutical industry contends it educates the medical profession and the public about its drugs and the conditions they treat, and many doctors and medical

[110] Melina Sherman, "How to Train Your Opioid Consumer," *Communication, Culture & Critique* Vol. 10 (2017), Pg. 599.

[111] Even today, these educational efforts are cited as justification for Purdue's actions. *See* Eric Russell, "Portrayed as villain in TV series about opioid crisis, ex-U.S. attorney for Maine says he didn't sell out," Portland Press Herald, February 27, 2022, *available at*: https://www.pressherald.com/2022/02/27/portrayed-as-villain-in-tv-series-about-opioid-crisis-ex-u-s-attorney-for-maine-says-he-didnt-sell-out/ ("McCloskey said the scene depicts an inaccurate timeline and he was especially disappointed with the insinuation that he was paid by Purdue to keep quiet. 'There's no truth to that whatsoever,' he said. 'Purdue did a number of things I asked them to do. They took a pill off the market because I asked them to do it. They worked on tamper-proof prescription pads. *They spent millions producing educational brochures*.'") (emphasis added).

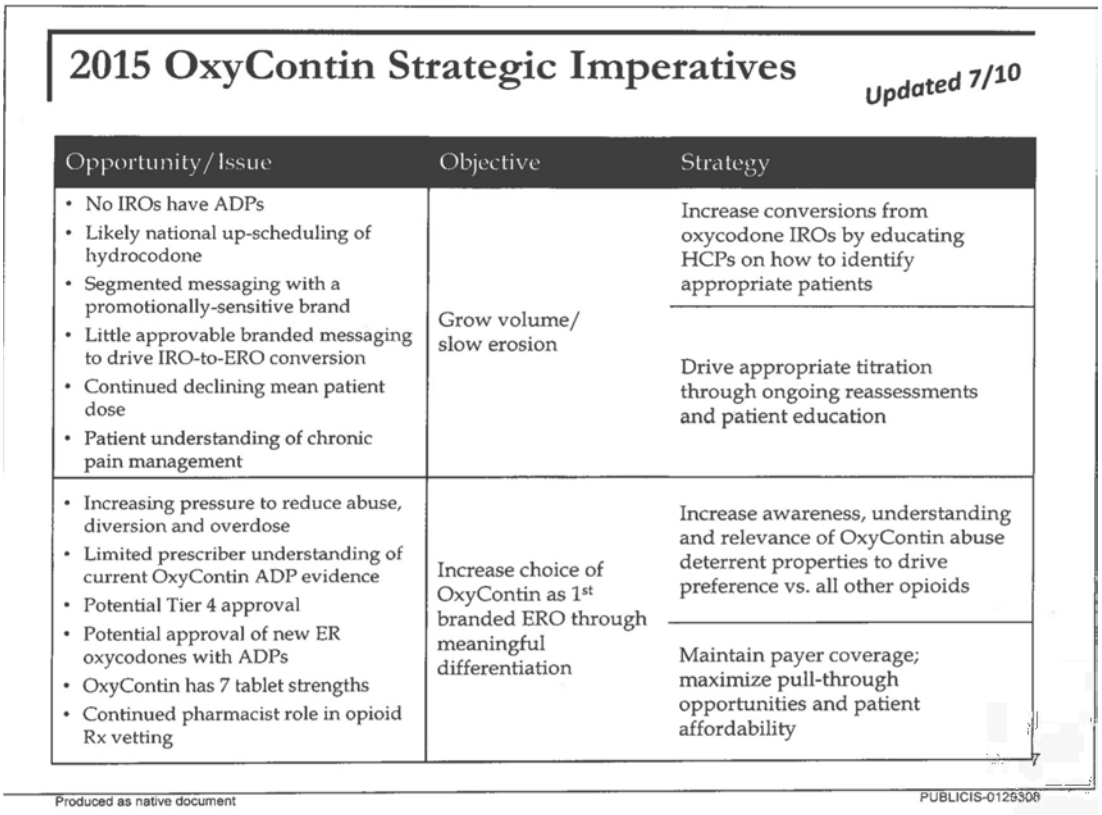
[112] Melina Sherman, "How to Train Your Opioid Consumer," *Communication, Culture & Critique* Vol. 10 (2017), Pg. 599.

[113] Dr. Marcia Angell, *The Truth About the Drug Companies*, Random House, 2004, Pg. 135.

> institutions – all recipients of the industry's largesse – pretend to believe it. So does the government. But "education" comes out of the drug companies' marketing budgets. That should tell you what is really going on.

207. Publicis employee Karl Tiedemann summed it up tidily, stating that the work Publicis was doing for Purdue was "not about education, but persuasion."

208. A 2015 Publicis presentation backed up Tiedemann's statement. It identified "patient education" and "increase[ing] awareness as the "strategies" to achieve the "objectives" of "grow[ing] volume" in light of, among other things, "increasing pressure to reduce abuse, diversion, and overdose":



2015 OxyContin Strategic Imperatives *Updated 7/10*

Opportunity/Issue	Objective	Strategy
• No IROs have ADPs • Likely national up-scheduling of hydrocodone • Segmented messaging with a promotionally-sensitive brand • Little approvable branded messaging to drive IRO-to-ERO conversion • Continued declining mean patient dose • Patient understanding of chronic pain management	Grow volume/ slow erosion	Increase conversions from oxycodone IROs by educating HCPs on how to identify appropriate patients Drive appropriate titration through ongoing reassessments and patient education
• Increasing pressure to reduce abuse, diversion and overdose • Limited prescriber understanding of current OxyContin ADP evidence • Potential Tier 4 approval • Potential approval of new ER oxycodones with ADPs • OxyContin has 7 tablet strengths • Continued pharmacist role in opioid Rx vetting	Increase choice of OxyContin as 1st branded ERO through meaningful differentiation	Increase awareness, understanding and relevance of OxyContin abuse deterrent properties to drive preference vs. all other opioids Maintain payer coverage; maximize pull-through opportunities and patient affordability

Produced as native document PUBLICIS-0126306

209. Moreover, unbranded marketing schemes like the one in which Ms. Grey unwittingly participated have a broader purpose of creating an information ecosystem designed to

benefit the interests of pharmaceutical companies. As Verilogue noted, by "shaping the dialogue," one can "shape the future."[114]

210. Dr. Sherman explained,

> This practice of dispersing branding materials in new contexts is emblematic of what Dumit (2012) has referred to as "strategic ubiquity," a tactic in which companies attempt to create a "universe" of syndicated and sponsored content through forming alliances with advocacy groups and developing partnerships with other influential third parties. For potential customers navigating this landscape, *every piece of information they read or hear about inevitably directs them toward specific actions that will serve the benefit of the company*.[115]

211. The strategic intent of these campaigns, then, is "to construct an echo-chamber of pro-opioid information."[116]

212. One example of this echo-chamber is Publicis' groundbreaking work with *regulators* on their own opioid marketing campaigns. In 2018, Razorfish Health partnered with the FDA's Center for Drug Evaluation and Research (CDER) to design the "Search and Rescue" campaign, which "makes innovative use of optimized search and direct email to reach family physicians, physician assistants and nurse practitioners, and in states with the highest opioid prescribing rates."[117] Razorfish's campaign for the FDA was designed to further the same educational messages Purdue was espousing, to "equip prescribers to be proactive in identifying and helping patients at risk for prescription drug abuse."[118]

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[114] *See infra,* fn. 493 and accompanying text.
[115] Melina Sherman, "How to Train Your Opioid Consumer," *Communication, Culture & Critique* Vol. 10 (2017), Pg. 603. (*citing* Dumit, J. *Drugs for life: How pharmaceutical companies define our health*. Durham, NC: Duke University Press) (emphasis added).
[116] Melina Sherman, "Opiates for the masses: constructing a market for prescription (pain)killers," *Journal of Cultural Economy*, Vol. 10, Issue 6, 2017, *available at*: https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010
[117] *See* https://drugfree.org/newsroom/news-item/partnership-drug-free-kids-announces-relaunch-search-rescue-opioid-prescriber-education-campaign-website/
[118] *Id.*

213. In other words, Publicis was able to deliver Purdue messages through alternative channels, including not only unbranded websites, but through the mouthpiece of *Purdue's regulator*, the United States Food and Drug Administration, as well. *That* is an echo-chamber.

4. Qui audet adipiscitur

214. "By nature, healthcare advertising provides a crutch to advertisers and marketers in the form of industry guidelines and regulations. We're quick to point out why we *can't* do something, rather than eager to question how we could make something work within those boundaries," pronounced Publicis Health Media's Media Director, Eric Delash.[119]

215. Instead, Delash encouraged pharmaceutical marketers to "embrace risk":[120]

> Challenge the status quo. Disrupt the norm. Create your Gritty. Embrace strategic risk and drive real innovation in healthcare marketing.

216. Delash's dashing attitude is reminiscent of prior rakish campaignors. "Who dares wins," chose Sir David Stirling before him.[121] Naturally, Publicis has long embodied the principles espoused in its Media Director's blog post. Indeed, Publicis has embraced risk and dared greatly on behalf of its clients. In 2016, Publicis submitted proposed work for the aforementioned TeamAgainstOpioidAbuse.com website, as well as a separate campaign for Hysinglia that it had pitched to Purdue, for consideration in the category of "Most Daring Campaign" in Medical Marketing and Media's annual industry awards.[122]

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[119] Eric Delash, *Healthcare Marketers Must Embrace Risk to Innovate*, Publicis Health Media Blog, December 13, 2018, *available at*: https://www.publicishealthmedia.com/perspective/healthcare-innovations/

[120] Eric Delash, *Healthcare Marketers Must Embrace Risk to Innovate*, Publicis Health Media Blog, December 13, 2018, *available at*: https://www.publicishealthmedia.com/perspective/healthcare-innovations/

[121] *See* David Stirling: The Phantom Major, *National Army Museum*, *available at*: https://www.nam.ac.uk/explore/david-stirling (recounting the origin of the motto of the British Special Air Service – *Qui audet adipiscitur* – during World War II); *see also*: https://en.wikipedia.org/wiki/Who_Dares_Wins

[122] Incredibly, that year, "*MM&M's* esteemed and independent panel of judges elected not to award a Gold for Most Daring Campaign… While some excellent and creative unsold work was entered, the judges felt that none of the submissions were precisely 'daring' enough, according to the judging criteria, to receive the top honor." Tanya Lewis, *Most Daring Campaign of 2016*, Medical Marketing and Media, October 6, 2016, *available at*: https://www.mmm-online.com/mmm-awards/most-daring-campaign-of-2016/ Not *all* who dare, win.

5. Coda

217. Success is determined by what is being measured. In one sense, Purdue was an inordinately profitable account for Purdue. Publicis' relationship grew from its start in 2010 to encompass practically all branded marketing business from Purdue six years later. By 2016, Publicis was the agency of record for OxyContin, Butrans, Hysinglia, and Targiniq. "The growth we continue to see in this business is phenomenal," congratulated a Publicis group president to the Purdue team. On March 22, 2016, John Dwyer emailed Karl Tiedemann to let him know that the expected annual revenue from Purdue for that year was approximately $12 million. "Oh boy," replied Tiedemann. The Subject line of the email thread was "We're gonna need a bigger boat." In that sense, Publicis was very successful.

218. Viewed differently, Publicis' daring work was outrageously successful for Purdue and, more to the point, the Sacklers. After 2013, the goal of *E2E* was to [redacted][123] and this Publicis did with great success. The Sackler Strategy that Publicis sold yielded large amounts of money available for distribution from Purdue to the Sackler family for over a decade. In that sense, Publicis was very successful.

219. In another sense, Purdue itself ended up bankrupt and, just like its parent, the Purdue Frederick Co., before it, a convicted felon. This might be something other than success.

220. On October 20, 2020, Purdue— Publicis's co-conspirator—agreed with the United States Department of Justice to plead guilty to improper marketing of OxyContin and other opioids again (the "2020 Settlement Agreement"). This time the plea agreement concerned conduct from 2010 to 2018. The agreement includes $8.3 billion in penalties from Purdue and $225 million from the Sackler family.

[123] PPLPC018000873870.

221. Purdue pled guilty to a dual-object conspiracy to defraud the United States and to violate the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 353, violating anti-kickback laws, and "using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids—frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America for decades."

222. The new plea agreement did not identify Purdue's co-conspirators, but Purdue's new guilty plea concerned Covered Conduct (as defined in the plea agreement) that directly implicates Publicis in the conspiracy, including the same conduct described in this Complaint.

G. Publicis and Other Opioid Manufacturers

223. Publicis' role in the propagation of the opioid epidemic extends far beyond its work with felons. During the pendency of its long-term relationship with Purdue, and their joint efforts to grow the *overall* opioid market, Publicis also partnered with Endo, Teva, Janssen, and others to market those clients' opioid brands. While it sought to grow the overall pie, Publicis also endeavored to grow each slice. It attacked the problem from both angles. And in doing so, it deployed many of the same tactics, at the same time, for numerous competing opioid brands. If some of the following paragraphs appear redundant, there is a reason. Lots of manufacturers' opioid marketing strategies looked a lot alike. Publicis was a common denominator.

1. Endo

224. Publicis' Saatchi & Saatchi unit ("Saatchi") was the Agency of Record for Opana, Endo Pharmaceutical's branded oxymorphone product. As described above, Opana is the same molecule as Endo's previous product – Numorphan – depicted in the film *Drugstore Cowboy*.

225. With the launch of Opana, Endo decided it was time for history to repeat itself. After Opana's approval in 2006, Endo solidified its position as a pain specialist among manufacturers. By 2012, Endo's opioid sales accounted for approximately $403 million of its $3

billion in revenue, more than 10% of its total sales. From 2010 to 2013, total Opana ER revenue alone exceeded $1.1 billion.

226. Opana and Numorphan were both oxymorphone. The brand name was the only thing that changed.[124] What Endo removed from the market in 1979 due to abuse concerns, it re-introduced 27 years later. After 2006, Opana was on occasion referred to as "blue heaven," or, more to the point, "new blues."[125]

227. In 2017, Endo would once again remove its branded oxymorphone product from the market, and for the same reason. Endo's abuse-deterrent formulation of Opana was removed at the request of the FDA due to acute concerns about its abuse potential.

i. Championing the Molecule

228. Publicis touted its new work for Endo Pharmaceuticals as one of its "main wins" of new business in 2018.[126] But Publicis' relationship with Endo already dated back more than decade. [redacted].[127] [redacted].[128]

229. [redacted]

[124] Literally, the only difference was the name. *See* ENDO_OPIOID_MDL-00863548 ("[redacted]." (emphasis added)).

[125] https://www.deadiversion.usdoj.gov/drug_chem_info/oxymorphone.pdf

[126] *See* https://www.publicisgroupe.com/en/news/press-releases/publicis-groupe-2018-annual-results. Publicis also touted its work with co-Defendant Allscripts as a "main win." *Id.*

[127] ENDO-OPIOID_MDL-02090726

[128] ENDO_FLAG-01075412

[redacted]

[redacted][129]

230. [redacted]

[redacted]

[redacted][130] [redacted]

[redacted][131]

231. [redacted]

[redacted]

[redacted][132]

[129] ENDO_OPIOID_DEPMAT-000068238, at 000068258.

[464] ENDO_OPIOID_DEPMAT-000068238, at 000068255, 00068256. [redacted] ENDO-CHI_LIT-00446003

[131] ENDO_OPIOD_MDL-02017196.

[132] ENDO_OPIOID_MDL-03656526

232. [redacted][133]

ii. "Durable Efficacy"

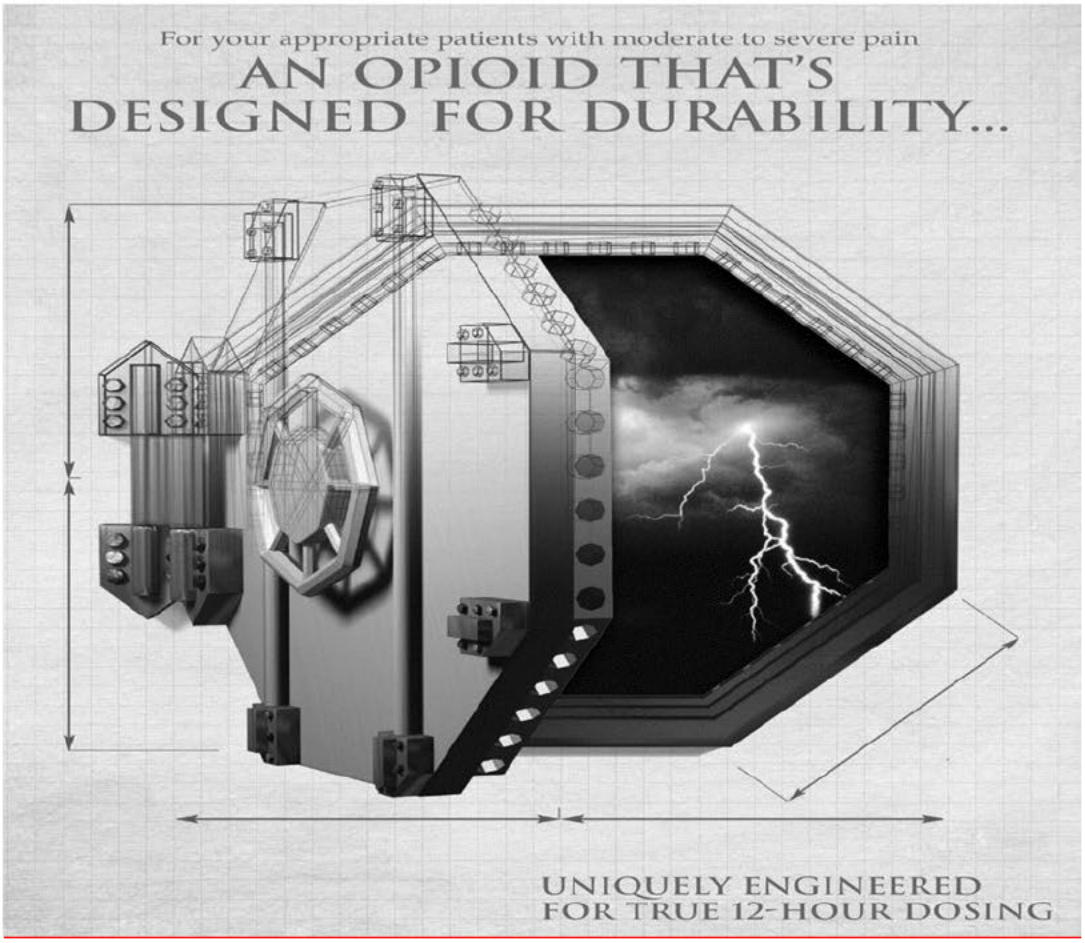
233. With respect to 12-hour dosing, the Federal Trade Commission has observed, "Compared with immediate-release oxymorphone formulation, oxymorphone ER provides longer-lasting, 12-hour pain relief that allows the patient to take fewer pills each day."[134] The problem, however, is that "in order to reduce dose frequency, each long-acting opioid carries more active pharmaceutical ingredient than its short-acting counterpart. This makes long-acting opioids such as Opana ER subject to abuse; crushing and ingesting the pills immediately releases the larger amount of active ingredient into the bloodstream."[135]

234. With respect to 12-hour dosing, [redacted][136] Separately, [redacted]

[133] ENDO_FLAG-01075147
[134] *See* Complaint, Federal Trade Commission v. Endo Pharmaceuticals, Inc. et al., No. 1:21-cv-217-RCL (D.D.C.) at Paragraph 57, *available at*: https://www.ftc.gov/system/files/documents/cases/003_2021.03.02_revised_redacted_complaint.pdf
[135] *See* Complaint, Federal Trade Commission v. Endo Pharmaceuticals, Inc. et al., No. 1:21-cv-217-RCL (D.D.C.) at Paragraph 57, *available at*: https://www.ftc.gov/system/files/documents/cases/003_2021.03.02_revised_redacted_complaint.pdf
[136] ENDO_FLAG-00911443

[redacted][137][redacted]

[redacted][138]



iii. Targeting Patients; Targeting Prescribers Part II

235. The targeting work that Publicis's Rosetta performed for Purdue, described *supra.*, was done for other clients as well. [redacted]

[137] ENDO_FLAG-01075147
[138] ENDO_FLAG-00911567

[redacted][139][redacted][140][redacted][141][redacted][142][redacted][143]

236. Whether young or old, opioid naïve or an experienced user exhibiting signs of increasing opioid tolerance; or whether the pain was emanating from cancer or construction labor, [redacted]

237. [redacted] For example, [redacted][144][redacted]

[139] ENDO_FLAG-00915025
[140] ENDO_FLAG-00915027
[141] ENDO_FLAG-00915029
[142] ENDO_FLAG-00915031
[143] ENDO_FLAG-00915033
[144] ENDO_OPIOID_MDL-02072698.

[redacted][145] Accordingly, [redacted]

[redacted][146]

238. Also in 2007, [redacted]

[redacted][147]

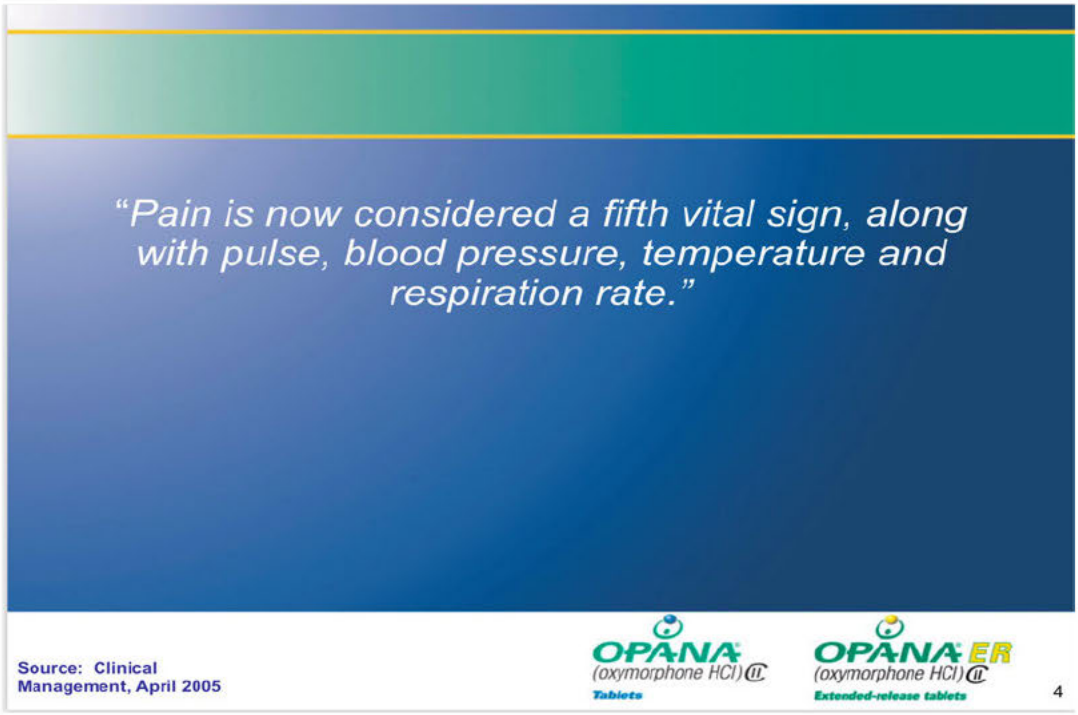
Saatchi relied on the fact that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) had recently adopted pain to as "the fifth vital sign," and now required hospitals to assess and treat patients' pain as a matter of course.[148] JCAHO "mandated that hospitals poll each of their patients at the end of their stay about whether their pain had been adequately treated."[149]

239. The scores that the hospitals received were[150] existentially important to the hospitals seeking to maintain their accreditation. "A low score puts a hospital in jeopardy of being ruled ineligible for Medicaid reimbursements."[151]

240. [redacted]

[redacted].[152]

[145] ENDO_OPIOID_MDL-02072698.
[146] ENDO_OPIOID_MDL-02072698.
[147] ENDO-NY_00625759.
[148] Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, "Inside the opioid industry's marketing machine," *Washington Post*, December 6, 2019, *available at*: https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/
[149] Melina Sherman, "Opiates for the masses: constructing a market for prescription (pain)killers," *Journal of Cultural Economy*, Vol. 10, Issue 6, 2017, *available at*: https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010
[150] JCAHO has since abandoned the idea that pain is the fifth vital sign.
[151] Melina Sherman, "Opiates for the masses: constructing a market for prescription (pain)killers," *Journal of Cultural Economy*, Vol. 10, Issue 6, 2017, *available at*: https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010
[152] ENDO-NY_00625759.



241. [redacted][153]

242. The idea was simple: prescribe Opana, and you won't have to worry about low JCAHO scores. "It suffices to say that this system incentivizes the use of drugs – as reliable, fast-acting opioids for (temporarily) warding off the experience of pain. It is telling, after all, that the uptake of these new systems and instruments of objectively measuring the subjective experience of pain have paralleled steep increases in opioid prescriptions."[154]

[153] ENDO-NY-00625759

[154] Melina Sherman, "Opiates for the masses: constructing a market for prescription (pain)killers," *Journal of Cultural Economy*, Vol. 10, Issue 6, 2017, *available at*: https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010

iv. Beyond Saatchi: Endo's Broader Relationship with Publicis

243. Saatchi wasn't Publicis' only source of revenue from Endo. In January of 2012, [redacted].[155]

244. A few months later, in April of 2012, Endo [redacted][156] [redacted][157]

245. Endo was keen on getting prescribers to switch from drugs like Vicodin to long acting opioids like Opana ER. [redacted] as well as "[redacted]"[158] [redacted][159]

[155] ENDO-OPIOID_MDL-03744169.
[156] ENDO0111659
[157] ENDO0111708
[158] ENDO0111708
[159] ENDO0111708

2. Teva

246. Teva Pharmaceuticals ("Teva") also availed itself of Publicis' myriad services. Teva sold Fentora, a fentanyl buccal tablet, after it acquired Cephalon, Inc. – Fentora's original manufacturer – in 2011.[160] The fentanyl pill was authorized by the FDA for use in the treatment of breakthrough pain in cancer patients receiving opioid treatment and who have become tolerant to it.[161] By 2008, [redacted][162] [redacted][163]

247. From the outset, [redacted][164] Nonetheless, [redacted][165]

248. [redacted]

[160] *See* https://www.fiercepharma.com/pharma/teva-completes-acquisition-of-cephalon

[161] *See* https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fentanyl-buccal-tablets-marketed-fentora-information

[162] Publicis acquired Verilogue, which began as an independent company in 2006, in 2013. *See* *https://www.benzinga.com/pressreleases/13/12/tr4138223/publicis-groupe-acquisition-of-verilogue*

[163] TEVA_MDL_A_01061669

[164] TEVA_MDL_A_01061669 (emphasis in original)

[165] TEVA_MDL_A_01061669

[redacted][166]

249. By October 2009, [redacted][167] [redacted][168] [redacted][169] Upon information and belief, [redacted] in this context refers to [redacted][170]

250. Notably, [redacted][171] [redacted] Upon information and belief, [redacted]

[166] TEVA_MDL_A_01533872
[167] TEVA_MDL_A_01091399
[168] TEVA_CHI_00001592
[169] TEVA_CHI_00001592
[170] TEVA_MDL_A_00721323 ([redacted])
[171] TEVA_MDL_A_00721323

[redacted]

251. The following year, [redacted].[173]

252. [redacted].[174]

253. [redacted]."[176] [redacted]

[redacted]."[177] [redacted]

[172] TEVA_MDL_A_02004878
[173] TEVA_MDL_A_02004912
[174] TEVA_MDL_A_02769828
[175] TEVA_MDL_A_08670617
[176] TEVA_MDL_A_02769830
[177] TEVA_MDL_A_02769830. Subsys was a fentanyl spray product sold by competitor Insys Therapeutics. *See* "Founder and Former Chairman of the Board of Insys Therapeutics Sentenced to 66 Months in Prison," Press Release, FDA, January 23, 2020, *available at:* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/founder-and-former-chairman-board-insys-therapeutics-sentenced-66-months-prison

[redacted][178]

254. [redacted][179] [redacted].[180]

255. This [redacted] work was eerily similar to the work Publicis performed for Purdue during the same time period in furtherance of *E2E*, as described *supra*.

256. On March 3, 2014, [redacted].[181] The following year, [redacted][182]

Publicis' comprehensive and detailed knowledge of the market for fentanyl products extended to Lazanda, another fentanyl spray initially manufactured by Archimedes Pharma and subsequently purchased by Depomed, Inc. in 2013. Publicis Touchpoint Solutions was contracted to provide Depomed "15 full-time sales representatives employed by Publicis but dedicated to us" to market Lazanda. Form 10-Q, Depomed, Inc. dated August 8, 2013, at pg. 21.

[redacted] TEVA_MDL_A_06478770. Lazanda is indicated for treatment in cancer patients. *See https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022569s005lbl.pdf*). TEVA_MDL_A_06478770.

[178] TEVA_MDL_A_02769830

[179] TEVA_MDL_A_08670617

[180] TEVA_MDL_A_08670617

[181] TEVA_MDL_A_11132793

[182] TEVA_MDL_A_8649676

257. As one Teva executive explained [redacted][183]

258. In November 2015, [redacted].[184] By the end of the year, [redacted].[185]

259. The Teva account was important to Publicis, and [redacted].[186]

260. A few months later, [redacted][187]

[redacted]

3. Johnson & Johnson/Janssen

261. Arista Marketing (hereinafter "Arista") was a Publicis company eventually folded into Publicis Touchpoint Solutions. Arista specialized in "multi-channel physician access above

[183] TEVA_MDL_A_08650706
[184] TEVA_NY_00095129
[185] TEVA_MDL_SF_00044499
[186] TEVA_MDL_A_08960291
[187] TEVA_MDL_A_08734851

and beyond face-to-face detailing."[188] "We create live conversations with physicians and other healthcare professionals, ranging from 2-minute teledetails to 12-minute web-based video details," Arista explained."[189]

262. In 2009, [redacted][190]

263. Nucynta was Janssen's branded tapentadol product. Nucynta was first approved as a Schedule II controlled opioid agonist tablet and oral solution in 2008 and indicated for "relief of moderate to severe acute pain in patients 18 years of age or older."

264. [redacted]

265. [redacted]"[191] [redacted]"[192]

[188] Publicis Strategic Solutions Group, "Arista Marketing Associates Rolls Out Multichannel Physician Access Program for Leading Pharma Co.," June 11, 2009, PRLOG, *available at*: https://www.prlog.org/10256062-arista-marketing-associates-rolls-out-multichannel-physician-access-program-for-leading-pharma-co.html

[189] Publicis Strategic Solutions Group, "Arista Marketing Associates Rolls Out Multichannel Physician Access Program for Leading Pharma Co.," June 11, 2009, PRLOG, *available at*: https://www.prlog.org/10256062-arista-marketing-associates-rolls-out-multichannel-physician-access-program-for-leading-pharma-co.html

[190] JAN-MD-00121873

[191] JAN-MND-00106720

[192] JAN-MND-00106720

[redacted][193]

266. [redacted][194]

267. In 2010, [redacted][195] [196] [redacted][197]

268. [redacted][198] [redacted][199]

269. Three years later, [redacted][200] Indeed, by 2013 [redacted]

[193] JAN-MND-00106720
[194] TEVA MDL A 13645931 at pg. 11-12.
[195] In 2011, Janssen obtained approval for a long-acting version Nucynta ER, which was indicated for "management of moderate to severe chronic pain in adults and neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults."
[196] JAN-MS-00018344 at 18368
[197] JAN-MS-00018344 at 18368
[198] JAN-MS-00772421 at 2, 5.
[199] JAN-MS-00772421 at 6.
[200] JAN_MS_01093081; JAN_MS_01093079

[redacted], while simultaneously working for competing products manufactured by others.

4. Servicing Manufacturers in Groups

270. Publicis did more than perform discreet work for individual opioid manufacturers; it crafted industry-wide marketing efforts to boost sales not only of individual opioid products, but of opioids *generally*. A rising tide lifts all boats. Or, to borrow the Purdue's executive's analogy, Publicis worked to "make the pie bigger for all."[201]

271. Accordingly, in addition to maintaining separate client relationships with multiple opioid manufacturers, Publicis also worked for industry-wide groups to coordinate marketing and advertising related to opioids, broadly. [redacted]

272. Likewise, [redacted][202]

[201] *See supra.* at Paragraph 90; Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, "Inside the opioid industry's marketing machine," *Washington Post*, December 6, 2019, *available at*: https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/

[202] JAN-NYDFS-0000123744

5. Servicing Demand on the Comeback[203] – Publicis and Orexo AB

273. The cognitive dissonance within Publicis as it embarked upon its work with Purdue on *E2E* must have been palpable. Three months after Publicis was working on OxyContin coupons, Swedish pharmaceutical company Orexo AB announced that the U.S. Food and Drug Administration had approved Zubsolv, its drug designed to treat opioid addiction. Zubsolv is a combination of buprenorphine and naloxone. At the time of Zubsolv's launch in 2013, Orexo projected peak sales of the drug to exceed $500 million, annually.

274. But Orexo did not have a significant presence in North America when Zubsolv was approved. It did not have its own sales force in North America that could market its drug. As the most attractive market in which to sell opioid dependency treatments, Orexo desired to partner with someone who had the expertise and capacity to successfully launch Zubsolv in the United States.

275. On July 1, 2013, Orexo announced "that the company has entered into a commercial partnership with Publicis Touchpoint Solutions for the launch of Zubsolv in the United States… Publicis Touchpoint Solutions will be responsible for the execution of all field-based promotion activities through dedicated sales representatives and medical support to health care practitioners through deployment of a dedicated medical scientific liaison team."[204]

276. In announcing the partnership, Orexo Chief Executive Officer Nikolaj Sorensen emphasized Publicis' "knowledge of the opioid dependence therapeutic area," in addition to its

[203] *See* Chris Rock, *Bigger & Blacker*, HBO TV Special, July 10, 1999, CR Enterprises, 3 Arts Entertainment, Production Partners, *available at*: https://www.youtube.com/watch?v=RRN3d5S_MTk ("There ain't no money in the cure; the money's in the medicine. That's how you get paid… on the comeback. That's how a drug dealer makes his money. On the comeback.")

[204] "Orexo Forms a Commercial Partnership with Publicis Touchpoint Solutions for Launch of Zubsolv in the US," July 1, 2013, *available at*: https://www.businesswire.com/news/home/20130701005515/en/Orexo-Forms-a-Commercial-Partnership-with-Publicis-Touchpoint-Solutions-for-launch-of-Zubsolv™-in-the-US

expertise with "similar product launches," as primary reasons Orexo chose Publicis to be its partner.

277. As described in detail above, Publicis did indeed have expertise with similar product launches. While its sales representatives in Publicis Touchpoint Solutions were diligently selling Zubsolv for Orexo, Publicis worked just as diligently through its other agencies with other opioid manufacturers to maximize the sales of the drugs that were the direct source of Zubsolv's indication. The same year it partnered with Orexo to launch Zubsolv, Publicis billed Purdue Pharma around $8 million for marketing work on OxyContin and other Purdue opioid products.

278. Most incredibly, Publicis began work on Purdue and McKinsey's *E2E* project **less than three months** after its partnership with Orexo was announced.

279. Through its work with Orexo, Publicis gained knowledge of the market opportunities created by widespread opioid dependency, and of the co-dependence of the markets for opioid treatments and opioid use disorder treatments.

280. As Orexo, Publicis' partner, described in its 2013 annual report, "[p]rescription painkillers containing opioids are highly addictive, and regular or long-term use can lead to physical dependence." Orexo further observed that "[m]any abusers begin by taking opioids orally," and that the misuse of opioid prescription drugs was a "growing problem," with "opioid dependence more common than the abuse or, or dependence on, any other type of prescription medication."

281. Describing the addressable market for Zubsolv, Orexo stated that the "cost of prescription opioid abuse, dependence and misuses in the US is estimated to exceed USD 56 billion per year," and further, "15,000 people die from opioid pain relievers each year in the US. Deaths from opioid pain relievers exceed those from all drugs and traffic accidents."

282. The conclusion was obvious:

> Zubsolv has entered a large and growing market. The current US market of products containing buprenorphine/naloxone amounts to approximately USD 1.9 billion, before rebates to payers, co-ay support and other discounts. The market continued to grow by 9 percent in value and 10 percent in volume during 2013. **Continued double-digit growth is likely in the years to come, and will be driven by the significant unmet medical need, the growing number of opioid dependent patients** as well as the impact of the Affordable Care Act.[205]

283. Publicis Touchpoint Solutions provided a contract sales force to Orexo through the second quarter of 2014, and continued to advise its client on Zubsolv sales through at least 2019.[206]

284. By 2015, Orexo stated flatly, "[t]here is no doubt opioid addiction has become one of the major health concerns in the US and a disease currently out of control."[207] The market for Zubsolv was booming, with an 83% increase in revenue compared to the prior year.[208]

285. Throughout its time selling a treatment for opioid use disorder, Publicis endeavored on multiple fronts, with multiple clients, to maximize the sales of opioids, the drugs that cause the condition that Zubsolv – another drug it was paid to sell – treats. The synergies were hard to beat. Publicis helped Orexo service a demand it had a principal role in creating and sustaining through its *contemporaneous* work on *E2E* and other projects. Indeed, without Publicis efforts promoting opioids for its other clients, there may not have been an addressable market for Orexo's product in the first place.

H. Alternative Channels: Publicis and Practice Fusion

286. In pharmaceutical sales, the traditional workhorse of sales and marketing campaigns is the individual sales representative calling on individual prescribers to meet in-person with them in order to extol the virtues of a given drug and encourage the doctor to prescribe more

[205] *See* http://mb.cision.com/Main/694/9557375/224609.pdf (emphasis added).
[206] *See* https://www.linkedin.com/in/susan-broadnix-8794bb7/
[207] *See* https://mb.cision.com/Main/694/9942119/491960.pdf
[208] *Id.*

of it to patients. Classically, this has been the primary channel through which a pharmaceutical company's message has been delivered to the intended audience.

287. Of course, there are alternatives to face-to-face meetings between doctors and sales representatives. In theory, wherever a prescriber's attention is focused at any given moment is a potential spot to deliver content to her. Over the past few decades, for instance, doctors increasingly interact with screens that they look at while at work. Forty years ago, doctors didn't walk around their offices holding iPads, but they do now. This is an "alternative channel" through which a message can be delivered, and Publicis endeavored with its clients to create multi-faceted campaigns so that a prescriber would be surrounded, in effect, with pharmaceutical company messaging coming from all directions: the people he has lunch with, the speakers at conferences he attends, the ads on his screen, the search results on his computer when he uses Google to search for a condition state, etc.

288. There are lots of alternative channels. [redacted]

[redacted][209]

[209] PPLPC014000224450.

Channel	Potential Targets	Potential Tactics	Vendors	Cost	Impact
Associations	• Targets who are members	• Approved messaging; educational focus	• APS, AAPM, AAFP, ACP, AAOFP, AAPA, AAPM&R	Med	Med
EHR	• EHR-using targets	• POC messaging	• Practice Fusion	High	Med
			• AllScripts		
In-office	• High-value targets due to cost	• Customized wall charts	• McCallan Health	High	Med
			• Accent Health		
			• Media Health Network		
Surveys	• All targets	• ATU-style questions	• WorldOne Interactive	Low	Med
Nurse Focus	• All NP targets	• Same messaging as MD	• RNSights	Med	High
Pharmacist Focus	• All Pharmacy targets	• ADF/access messaging	• SK&A	Med	Med
MC Focus	• All MC targets	• ADF/access messaging	• SK&A	Med	Med
Contract Field Force	• IDNs	• Standard rep messaging	• Best MSLs	High	Med
Social	• All targets	• Educational messagings	• Doximity	Med	Med
			• QuantiaMD		
KOL Programs	• All targets	• KOL on-demand	• Synapse	High	Med
Conference Services	• Attendee lists	• High-value messaging	• Pain-related conferences	Med	High
Authenticated Website	• All targets	• High-value messaging	• UBM Medica	High	Med
eSample	• Sample-appropriate targets (Intermezzo)	• Sampling	• Physicians Interactive	High	Med
			• Doctor Directory		
Website	• All targets	• All messaging	• PurdueHCP.com	Med	High

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289. These channels, when utilized together as part of an overall package, constitute the overall "marketing mix" that Publicis, ZS, McKinsey and others continually endeavor to optimize and espouse as a "best practice," which is another way of saying that lots of the consultants' other clients do the same thing. [redacted], Publicis stood athwart the industry, in a position to advise their clients on which vendors to pick to best utilize these alternative channels.[210] In this way, as in others, Publicis served as a hub, or an intermediary connecting multiple participants in the overall efforts to market opioids to maximum effect.

290. "EHR" stands for Electronic Health Record. It is a relatively new marketing channel, and one whose growth was spurned by federal legislation in 2009 that encouraged doctors to adopt electronic record-keeping methods for patient records. As early as 2012, Publicis was working with Purdue to develop banner advertising and other types of content that could be placed

[210] Indeed, this position athwart the distribution channels is what being an AOR *is*.

in the EHR channel. This work continued at late as 2018, and Publicis, as AOR, also selected EHR vendors in which the content could be placed.

291. They chose Practice Fusion.

292. As the varieties of marketing channels above make clear, pharmaceutical marketing is complex. Publicis Health's Chief Digital Officer recently remarked on his complexity:

> When we think about our ecosystem, the complexity goes beyond just regulatory. We are in a complex ecosystem in the sense that we are marketing to two different audiences in a patient, and a physician. We're hoping that they come together and have a productive conversation, and in that conversation, we're hoping that they talk about the treatment that we're marketing to them. And that's complex, I don't think there's any other industry that is met with that challenge.[211]

293. This complexity creates reams of data. ZS Associates, the pharmaceutical sales and marketing consultancy, has described the "endemic challenge" facing the pharma industry: "It has a complex and circuitous sales process involving drug manufacturers, physicians, pharmacies, patients, and insurance companies. Each step in a buying process creates data – and more of it is being created every day."[212]

1. Electronic Health Records – A New Frontier

294. These data streams may be used as a tool. The data available and the information provided by EHR is all-encompassing in its breadth. As ZS Associates noted, "[t]he spectrum of data is almost unprecedented: lab results, diagnoses, prescriptions, patient compliance, physician notes, and follow-on or replacement prescriptions."[213] The result is that EHR data provides an end-

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[211] Ray Rosti, Chief Digital Officer of Publicis Health Media, December 7, 2020, available at https://www.youtube.com/watch?v=AG4HLlDSQ_A

[212] Steve Love, Sudhanshu Bhatnagar, Greg Rickman, and Jedy Wang, "The Value of EMR Data: Unlocking Insights That Drive Pharma Sales," *Journal of Pharmaceutical Management Science Association*, Spring 2016, *available at*: https://1library.net/document/zlewp5lq-value-emr-data-unlocking-insights-drive-pharma-sales.html .
In 2011, ZS touted Publicis' endorsement of its own product offerings, such as Javelin. *See* https://twitter.com/ZSAssociates/status/119892005756215297

[213] Steve Love, Sudhanshu Bhatnagar, Greg Rickman, and Jedy Wang, "The Value of EMR Data: Unlocking Insights That Drive Pharma Sales," *Journal of Pharmaceutical Management Science Association*, Spring 2016, *available at*: https://1library.net/document/zlewp5lq-value-emr-data-unlocking-insights-drive-pharma-sales.html.

to-end perspective of the entirety of a patient's journey from diagnosis of a disease through treatment and ultimately cure or death.[214]

295. This wealth of data can be used to sell more drugs. With the proliferation of electronic health data, vendors have arisen to aggregate and sell data sets and analytics platforms based on this data. These providers "now give pharma companies greater visibility than ever into its (*sic*) marketplace of buyers, consumers, and decision-makers – and the factors that drive sales."[215]

2. What Practice Fusion does

296. Practice Fusion was founded in 2005 as a vendor of free electronic health record storage (EHR) software. It "makes software that many doctors see on their devices. When you go into the exam room, your electronic records pop up on their screens."[216]

297. Practice Fusion's cloud-based EHR software platform serves tens of thousands of active health care providers in the United States, and the software is used during millions of physician-patient encounters each month. It is "the #1 cloud-based ambulatory EHR platform in the U.S.,[217] supporting 30,000 medical practices in delivering better care to 5 million patients a month. With a best-in-class satisfaction rate,[218] Practice Fusion is committed to delivering intuitive and easy-to-use health IT solutions to small, independent medical practices."[219]

298. The business model was daring; most EHR vendors – Practice Fusion's competitors – charge users to use their software platforms, typically in the form of a licensing fee. Practice

[214] *Id.*
[215] *Id.*
[216] Brian Mann, "Health Care Software Firm Fined $145M in Opioid Scheme With Drug Companies," *NPR*, February 1, 2020, *available at*: https://www.npr.org/2020/02/01/801832788/healthcare-software-firm-fined-145m-in-opioid-scheme-with-drug-companies
[217] SK&A, Report on Physician Office Usage of Electronic Healthcare Records Software (February 2016).
[218] Reaction Data, Report on EHR Satisfaction According To Physicians (January 2018).
[219] Practice Fusion Company Profile, https://www.practicefusion.com/about/

Fusion was different. Ryan Howard, founder and CEO of Practice Fusion, explained, "our product being free and web-based was incredibly unorthodox."[220]

299. The company didn't charge the doctors for these intuitive and easy-to-use health IT solutions. It was free to them.[221] Instead, Practice Fusion derived revenue from payments from pharmaceutical companies in exchange for ad space, and other marketing products like "clinical decisions alerts" (CDS) in its EHR software that served as advertisements for the pharmaceutical company's products.[222]

300. Practice Fusion marketed its platform to the pharmaceutical companies as a way to influence prescriber behavior. For instance, Practice Fusion's pitch materials to pharmaceutical companies indicated that a pain CDS could be aligned with that company's "brand objectives."

301. From the advertiser's perspective, this product offering was tantalizing. [redacted][223] [redacted][224] "Practice Fusion, the cloud-based

[220] Ryan Howard, CEO Practice Fusion, Cracking the Entrepreneur Code, September 26, 2011, *available at*: https://www.youtube.com/watch?v=JaTIgMUEc9Y&t=1067s

[221] "If something is free, you're the product." *See* Richard Serra, Carlota Fay Schoolman, *Television Delivers People*, 1973 ("The Product of Television, Commercial Television, is the Audience… Television delivers people to an advertiser."), *available at*: https://www.youtube.com/watch?v=LvZYwaQlJsg

[222] Christina Farr, "Practice Fusion, once headed for $1.5 billion valuation, ends in 'disappointing' fire sale," *CNBC*, January 8, 2018, *available at*: https://www.cnbc.com/2018/01/08/practice-fusion-acquired-by-allscripts-for-100-million-in-cash.html (""Rather than selling expensive licenses, the company makes money by showing ads to physicians that use the service.")

[223] *See* [redacted], TEVA_CHI_00437579.

[224] [redacted], TEVA_CHI_00437579.

electronic medical system, mirrors the real-life workflow of a doctor's office," explained John Mehta, Publicis Sapient's Chief Experience Officer from 2019 to 2020.[225]

302. The brand objectives that Practice Fusion pursued for Purdue and other opioid manufacturers included expanding the market share of a given company's extended-release opioids *as well as* growing the *overall* size of the ERO opioid market by targeting "opioid naïve" patients and patients that were on immediate release ("IRO") opioid therapies.

303. Practice Fusion's EHR platform provided Purdue and other opioid manufacturers a way to reach into the examination room and interact with the prescriber and the patient by utilizing the "wealth of data" available in EHR records[226] to deliver targeted messaging when and *when* it matters. Moreover, Practice Fusion provided its customers (pharmaceutical companies, not doctors) with "novel tools" to "drive appropriate care for patients with chronic pain," by utilizing private, individualized patient health care records in order to target the delivery of messages intended to increase overall ERO prescribing. The platform enabled Practice Fusion's customers to insert promotional messaging throughout the provider workflow, including during patient visits and "patient-centric provider targeting."[227] Practice Fusion provided these services to its customers so without patient or physician consent.[228]

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[225] John Maeda, "Better Health by Design: Making Healthcare Tech More Usable, Understandable And Profitable, *TechCrunch*, December 8, 2015, *available at*: https://techcrunch.com/2015/12/08/better-health-by-design-making-healthcare-tech-more-usable-understandable-and-profitable/. *See also* https://forward.recentiprogressi.it/en/magazine/number-17-places-of-care/articles/better-health-by-design/ (identifying Maehda as Publicis' Chief Experience Officer. According to LinkedIn, Maehda left Publicis Sapient in October of 2020. *See* https://www.linkedin.com/in/johnmaeda/).

[226] See PFDPA00000025-27 (noting the wealth of data gleaned from access to the medical records helped build a franchise to treat patients in pain "around the clock" and expand the data sets of conditions for which to prescribe opioids).

[227] *Id*. at 4.

[228] Press Release, Department of Justice, Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations, Practice Fusion Inc. Admits to Kickback Scheme Aimed at Increasing Opioid Prescriptions (Jan. 27, 2020), https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0

304. As early as 2012, Publicis was working with Purdue to develop banner advertising and other types of content, including CDS alerts, that could be placed within the EHR channel. This work continued at late as 2018, and Publicis, as AOR, also selected EHR vendors in which the content could be placed: Practice Fusion.

3. Publicis and Practice Fusion

305. Publicis piloted Practice Fusion to Purdue over years of working with both. In one sense, this is Publicis performing its role as AOR for Purdue. The AOR not only *creates* the content, but *places* it as well. The AOR acts as a distributor of the client's ads to people selling space in which to put them. A billboard on the side of an interstate, a prospective patient's TV screen, signage on the wall above the urinals in a barroom bathroom, a prescribers' iPad screen… it's all placement. Choosing the best places and putting Purdue's messages in them was part of Publicis' job as AOR.

306. One of the best spots, Publicis informed Purdue, was Practice Fusion. In the simplest of terms, Practice Fusion had advertising space to sell in the form of banner advertising and embedded features such as CDS alerts that could be placed within Practice Fusion's software programs that prescribers looked at on their screens throughout the day, and Publicis put some Purdue content there.

307. In October 2013, [redacted] [229] Practice Fusion's subsequent work with Purdue was

[229] PPLPC014000224450; PPLPC014000224448 ([redacted]

carried out in coordination and conjunction with Publicis, and as a part of the McKinsey's implementation of *E2E* alongside Purdue to [redacted][230]

308. Publicis even paid Practice Fusion's invoices on behalf of Purdue.

309. Publicis and Practice Fusion coordinated their work for Purdue. In April 2014, with *E2E* in full swing, Publicis' John Dwyer reached out to Practice Fusion's Jim Pantaleo to discuss some "aggressive EMR strategies" for Purdue, and focused on the point of prescription, when the doctor is deciding whether and what to prescribe to a patient. For doctors contemplating prescribing an immediate-release opioid (IRO), an ad featuring Oxycontin's 12-hour dosing would appear. A doctor contemplating an extended-release opioid (ERO) would see an ad touting OxyContin's formulary coverage. Dwyer also suggested a "reassessment" reminder appear within the EMR each time a patient receives a consecutive prescription for OxyContin, in which the prescriber would be reminded of Purdue's titration messaging, described above. Dwyer suggested four such "aggressive" strategies, and suggested that the strategies that have the "highest ROI" and are the best "Rx drivers" be reinvested in:

[230] PPLPC018000873870.

To: John Dwyer[john.dwyer@rosetta.com]
From: Jim Pantaleo
Sent: Mon 8/11/2014 9:49:51 AM (UTC-04:00)
Subject: RE: Purdue Brands - EMR Strategy/Ideas/Discussion

Thanks John. Checking in sounds like a good plan.
In the meantime, I will put together messaging examples of how others are targeting in the platform and send to you.
We may not have the exact strategic messaging tactics, but I believe all of the below can be executed.
I'll send by end of day; first thing tomorrow.
Jim

From: John Dwyer [mailto:john.dwyer@rosetta.com]
Sent: Monday, August 11, 2014 9:36 AM
To: Jim Pantaleo
Subject: Re: Purdue Brands - EMR Strategy/Ideas/Discussion
Hi Jim,
I agree, and I think we should try to check in with each other for a few minutes every other week or so while these programs are of high interest to Purdue.
Here are the 4 approaches we discussed on Friday's meeting. Again, with these approaches, the most helpful thing you can provide would be examples of other products that have used a targeting strategy to serve ads based on competitor brands or generics in the same category.
EMRs for EROs (addresses Conversion, Titration, opioids with abuse-deterrent properties (OADPs), Mgd Care)

- Pilot 3 aggressive EMR strategies in Q1 and quickly optimize and reinvest in the 1-2 highest ROI and Rx drivers

1. Target IRO oxycodone Rxs with branded OxyContin Q12h msg or unbranded ER teaser msg
2. Serve a "Reassessment" reminder msg each time pt receives consecutive OxyContin Rx
3. Target non-ADP Rxs with branded OxyContin ADP msg or unbranded ADP teaser msg
4. Target ERO Rxs with OxyContin MC coverage message or unbranded coverage teaser msg

Thanks again for coming by on Friday and sharing so much information.
John Dwyer
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310. Three months later, in July 2014, Publicis proposed that EHR channels be used to encourage conversion of immediate-release opioids (IRO) patients to extended-release opioids (EROs). This would have the effect of growing the overall size of the ERO market by creating new ERO users who previously were prescribed IROs. One idea was to target any patient who has been prescribed an IRO "multiple times (3 or 4) with a branded or unbranded message for OXC."

311. Consistent with the overall goals of *E2E*, Publicis encouraged Practice Fusion to help grow the ERO market by encouraging conversions of IRO users. Publicis informed Purdue that Practice Fusion had the relevant capabilities: the ability to deliver "Branded OxyContin & clinical messages… during patient eRx, patient Medication Selection… and edit patient Medication." Publicis' John Dwyer asked his colleagues whether Practice Fusion had "any kind of ROI or Rx impact metrics around these that they can share?"

4. Practice Fusion and Purdue

312. In April of 2013, Publicis agreed to place banner advertisements inside of Practice Fusion's EMR software for Purdue's products. The banner ads would appear when a prescriber was seeing a patient with certain health conditions, and the Purdue ads would appear with the patient's EHR suggested pain-related content—for instance, a reference to the patient's "pain symptoms." Three of the banner ads were for OxyContin, two were for Butrans.

313. After a few months, because of compliance concerns, Purdue paused the banner advertisement initiative, but in December 2013, Publicis made the case for continuing the initiative, and told Purdue, "Practice Fusion is the only partner that offers Banners within workflow prior to making a prescribing decision. Helps to increase awareness – and ultimately sales."[231]

314. Meanwhile, Practice Fusion continued to solicit business from Purdue directly. In May 2014, for instance, Practice Fusion sent a news article to Purdue about Practice Fusion's implementation of a CDS program for a vaccine manufacturer. The article was forwarded internally at Purdue to the new CEO, Mark Timney, who had been appointed CEO four months prior. Timney responded, "Thanks. The key is understanding how it grows or protects scripts."[232]

5. CDS Alerts: Circumventing No-Sees, Influencing Prescribing, Making Money

315. What is a CDS Alert? "CDS tools help doctors know when and how to provide certain types of treatments. In a world of voluminous information, these tools distill complex data into simple-to-read flowcharts and algorithms to guide prescribers. When based on scientific evidence these tools can be helpful. When not, then can mislead large numbers of doctors."[233]

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[231] Massachusetts Publicis Complaint Para. 103.
[232] Practice Fusion Information at Para. 28.
[233] Expert Report of Dr. Anna Lembke, Doc. 4889-1 at 74-75, *In re National Prescription Opiate Litigation*, Case No. 1:17-md-02804 (N.D. Oh.)(filed February 10, 2023)

316. A doctor using Practice Fusion's software would see a message "alerting the healthcare provider that, given the particular personal health information and circumstances of the patient before the provider at that moment, the provider should consider certain clinical information, perform certain tests or assessments, and complete certain documentation."[234]

317. Do CDS alerts work?[235] At a 2016 seminar for pharmaceutical companies put on by Ogilvy (another advertising agency, owned by Publicis competitor WPP), Practice Fusion presented, and gave the audience an example of the of power of the clinical decision support program:[236]

> Practice Fusion, a cloud-based EHR provider, offered an example in which it launched an obesity clinical decision support program. The HER notified physicians with messages at the point of care about recording patients' BMI stats and, if high, noting a treatment plan. The program reached more than 50,000 physicians and 3.7 million patients resulting in 25,000+ more patient plans, **which was a 5-fold increase.**

318. Why do CDS alerts work? Well, "the closed system of EHR's… means the marketing and communications from pharma to physicians are not scattershot web ads, but much more targeted inside communications that can inform doctors at a critical moment."[237] "Presenter after presenter noted not only the value of EHRs but also that using them needs to be thought of as a strategy, not just a tactic or channel."[238]

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[234] Practice Fusion Information at Para. 17.

[235] "Work," in the sense of making money for the pharmaceutical company. ROI is the relevant metric. If the product cannot increase sales for the pharmaceutical company that pays Practice Fusion, no pharmaceutical company will pay Practice Fusion money, and the company would go broke or have to "pivot" to another busines model and pray for rain. Practice Fusion was not a non-profit, nor a B Corp. It was in business to make money.

[236] Beth Snyder Bulik, "Ogilvy CommonHealth takes deep dive on EHR as a marketing strategy for pharma clients," *Fierce Pharma*, May 9, *available at*: https://www.fiercepharma.com/marketing/ogilvycommonhealth-takes-deep-dive-ehr-as-a-marketing-strategy-for-pharma-clients (emphasis added).

[237] Beth Snyder Bulik, "Ogilvy CommonHealth takes deep dive on EHR as a marketing strategy for pharma clients," *Fierce Pharma*, May 9, *available at*: https://www.fiercepharma.com/marketing/ogilvycommonhealth-takes-deep-dive-ehr-as-a-marketing-strategy-for-pharma-clients (emphasis added).

[238] Beth Snyder Bulik, "Ogilvy CommonHealth takes deep dive on EHR as a marketing strategy for pharma clients," *Fierce Pharma*, May 9, *available at*: https://www.fiercepharma.com/marketing/ogilvycommonhealth-takes-deep-dive-ehr-as-a-marketing-strategy-for-pharma-clients (emphasis added).

319. Could CDS alerts be used as a strategy (or tactic) to maximize sales of a controlled substance that the planners know is causing widespread addiction, abuse, and death? Yes.

320. Were they? They were. According to Dr. Anna Lembke, the Pharmaceutical Opioid Industry "contributed substantially to the paradigm shift in opioid prescribing through misleading messaging about the safety and efficacy of prescription opioids" that were disseminated through multiple channels including "clinical decision support tools."[239]

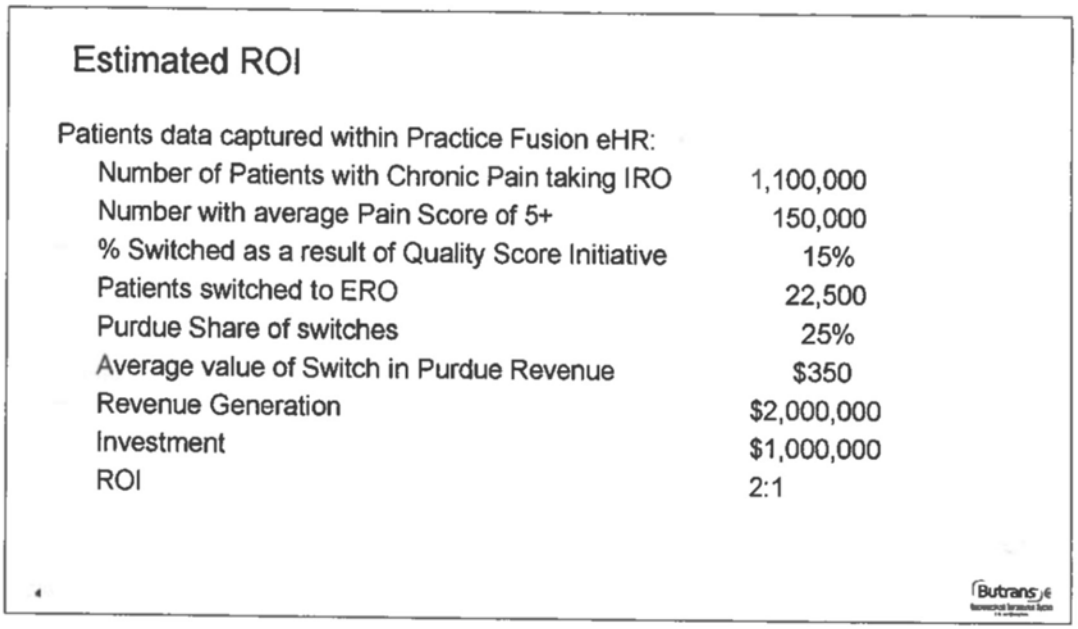
321. In late 2015, Purdue gave its approval to move forward with the Pain CDS alert program. Because the overall goal of the program was to increase the size of the *overall* ERO market, each of Purdue's three ERO brands split the cost of the Practice Fusion program.

322. By 2016, Purdue and Practice Fusion were working to use CDS alerts for the "objective" to "Grow ERO prescriptions within the Practice Fusion eHR." Publicis estimated that the return on investment (ROI) on the CDS alerts would be 2:1.[240] An additional $2 million in annual revenue was possible by using Practice Fusion to convert IRO patients to ERO patients, but it would cost $1 million annually in payments to Practice Fusion in order to obtain that additional revenue:

[239] Expert Report of Dr. Anna Lembke, Doc. 4889-1 at iv, *In re National Prescription Opiate Litigation*, Case No. 1:17-md-02804 (N.D. Oh.)(filed February 10, 2023)

[240] Practice Fusion performed its own ROI analysis of the Pain CDS program for Purdue, and estimated that Purdue would enjoy a decidedly rosier 5.8 to 7.8 times its cost. Practice Fusion Information at Para. 37. Just like Publicis, Practice Fusion was at all times focused on delivering ROI for Purdue. In an April 22, 2015, internal email, a Practice Fusion employee conceded, "Since this is being sent to a marketing audience the idea of ROI has to be part of the plan to justify the costs of the program." Practice Fusion Information at Para. 42.

Notably, this ROI analysis was left *out* of the written presentations that Practice Fusion provided to Purdue, as it would raise compliance concerns. "Don't include the ROI in the [written] proposal. We'll walk the client the ROI," advised the same employee who stated that "the ROI has to be part of the plan." Practice Fusion Information at Para. 43. Instead, Practice Fusion "voiced over" the "commercial impact" of its proposed program, instead of creating a paper trail.



Estimated ROI

Patients data captured within Practice Fusion eHR:	
Number of Patients with Chronic Pain taking IRO	1,100,000
Number with average Pain Score of 5+	150,000
% Switched as a result of Quality Score Initiative	15%
Patients switched to ERO	22,500
Purdue Share of switches	25%
Average value of Switch in Purdue Revenue	$350
Revenue Generation	$2,000,000
Investment	$1,000,000
ROI	2:1

Butrans

323. Practice Fusion and Purdue entered into a Statement of Work on March 1, 2016, to provide a CDS program "directed at chronic pain management treatment with immediate release opioids and chronically used NSAIDs."[241]

324. The contract stated that the "Parties agree and acknowledge that the collaboration project will follow national evidence-based guidelines, and will not encourage the prescribing or utilization of Purdue-specific product or services."[242] Both Practice Fusion and Purdue knew at the time of contract formation this mutual representation was false. In fact, "national evidence-based guidelines" such as the CDC Guidelines released on March 15, 2016, were known to the Parties while the CDS was designed and implemented, but those guidelines were ignored. Likewise, a 2016 *New England Journal of Medicine* article entitled "Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies counseled against the use of opioids for chronic pain, where the benefits of opioids were "much more questionable" than in the acute treatment context.

[241] Practice Fusion Information at Para. 75.
[242] Practice Fusion Information at Para. 78.

Purdue and Practice Fusion reviewed the article but ignored its conclusions. Instead, they designed the CDS alerts to *convert* users of IROs to EROs for long-term maintenance of chronic pain.

325. Purdue's marketing team – not Purdue's medical experts – worked with Practice Fusion to *design* the CDS and determine its functionalities. For instance, the CDS was designed to incorporate patient's Pain Score and a brief pain inventory ("BPI"), and Purdue's marketing staff also contributed to the design of the Care Plan options presented within the CDS, and the logic of the CDS software functionality itself.[243] "BPI can increase ERO use," Purdue noted.[244]

326. The CDS program was launched on the Practice Fusion platform in early July 2016. The final pain CDS contained three separate alerts: (1) the first alert urged the healthcare provider to record a pain score; (2) the second alert recommended that healthcare providers take a brief pain inventory ("BPI") of patients that met a certain threshold, for patients who had a chronic pain diagnosis, and for patient who recorded two or more pain scores of four or more in the previous three months (utilizing a zero to ten point-scale); (3) the third alert suggested the creation of a follow up plan to treat the patient's pain, which alert appeared when a patient reported a pain scale of four or higher within four months, or if a patient with chronic pain had a BPI contemplated.

327. The pain CDS alert implemented by Practice Fusion deviated from established medical guidelines by directing providers to record a treatment plan only when pain was classified as chronic or was above a certain threshold over a period of time. It did not incorporate the substance of the New England Journal of Medicine article from which the CDS sourced a list of treatment options.

328. Moreover. the Clinical Quality Measures ("CQM") performance standards require providers to record a treatment plan any time the pain assessment was documented as positive.

[243] Practice Fusion Information at Para. 90.
[244] Practice Fusion Information at Para. 91.

Contrary to accepted medical practice, the pain CDS alert listed EROs as a treatment option on equal footing with IROs and non-opioid therapy. Likewise, it also listed EROs as a treatment option for opioid naïve patients without regard to whether the provider had the adequate expertise to prescribe EROs.

329. As the CDS alerts went live, Practice Fusion kept Purdue updated on progress. Practice Fusion told Purdue that through November 30, 2016, the pain CDS alert had produced alerts during 21 million patient visits, involving 7.5 million patients and 97,000 healthcare providers.

330. Practice Fusion further indicated that since its Pain CDS alerts went into effect "there is a general shift toward EROs from IROs," the biggest impact recorded "within Emergency Medicine, Orthopedics, and Pain Medicine."

331. The Pain CDS alert was live on the Practice Fusion platform from early July 2016 to the spring of 2019. The Pain CDS alerted more than 230,000,000 times during this period. Physicians wrote hundreds of thousands of ERO prescriptions after one of the Pain CDS alerts had been triggered. Moreover, healthcare providers who received Practice Fusion's Pain CDS alerts prescribed EROs at a higher rate than those that did not.[245]

6. Guilty

332. In January 2020, Practice Fusion paid $145 million and entered into a deferred prosecution agreement with the Department of Justice for these CDS alerts and its work with Purdue.[246] Nine months later, Purdue pled guilty for conspiring with Practice Fusion to violate the

[245] *See* Practice Fusion Information, at Paragraph 115.

[246] Press Release, Department of Justice, "Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations, Practice Fusion Inc. Admits to Kickback Scheme Aimed at Increasing Opioid Prescriptions", Department of Justice (Jan. 27, 2020), *available at*: https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0 (describing Practice Fusion's conduct as "abhorrent" and noting Practice Fusion and Purdue "illegally conspired to allow [Purdue] to have its thumb on the scale at precisely

Anti-Kickback Statute by paying Practice Fusion for the CDS alerts which were intended to increase sales of Purdue's drugs.[247] Then, on March 8, 2021, Practice Fusion's former Director of National Accounts, Steven Mack, pled guilty to one count of attempting to obstruct a federal investigation into the relationship between Practice Fusion and Purdue.[248]

7. A Mea Culpa

333. "I was horrified."

334. So wrote Ryan Howard, co-founder and former Chairman and CEO of Practice Fusion, describing his reaction to "encountering some staggering news": "Practice Fusion, a company I founded in 2005 and left in 2015, had reached a settlement with the DOJ for suddenly partnering with an opioid manufacturer, and for encouraging doctors on the platform to prescribe opioids to patients."[249]

335. Howard "founded [Practice Fusion] in 2005 and was its Chairman and CEO until 2015… Under Ryan's leadership the company raised $134 million in capital from Kleiner Perkins Caulfied & Byers… Deerfield Management Company [and others] to fuel its rapid growth."[250]

336. Howard noted that Practice Fusion "advertised to doctors *230 million times* to prescribe opioids," and concluded that his "successors" fell "prey to the allure of capital over

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the moment a doctor was making an incredibly intimate, personal, and important decisions about a patient's medical care, including the need for pain medication and prescription amounts.")

[247] Press Release, "Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family," Department of Justice, October 21, 2020, *available at*: https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid

[248] Press Release, "Former Practice Fusion Sales Executive Pleads Guilty to Obstructing Government Investigations into Purdue Pharma and Practice Fusion," Department of Justice, March 8, 2021, *available at*: https://www.justice.gov/usao-vt/pr/former-practice-fusion-sales-executive-pleads-guilty-obstructing-government

[249] Ryan Howard, "How to Prevent Your Company from Being Used for Evil From a Founder Who's Been There," *Entrepreneur*, November 28, 2020, *available at*: https://www.entrepreneur.com/article/359624

[250] *See* https://www.practicefusion.com/practice-fusion-founders/

human lives."[251] He minced no words regarding the appropriate outcome for his "successors" at Practice Fusion for allowing the company to partner with Purdue: "Following my departure in 2015, my successors seemingly adopted a new mission – they allowed the [Purdue] partnership to take root – and for this, I suggest they experience the full retribution of our justice system." [252]

337. Howard suggested that other entrepreneurs and founders of companies look into registering as benefit corporations, or B corporations, in order to prevent their creation from "being used for evil." He also provided the following "full disclosure:"[253]

> I was never contacted by the DOJ, or any other authority, regarding Practice Fusion's investigations. Likewise, I was not part of any conversation with any opioid manufacturer while I was CEO. The referenced partnership occurred in 2016, after my departure, as detailed in the official DOJ Report (p. 18).

338. Like the Sackler's before him, Howard desired to distance himself from Purdue Pharma. But, as noted above, Practice Fusion's relationship began in the fall of 20*12*, and Howard was CEO for approximately 2 years while the company partnered with and serviced Purdue. In the fall of 2012, Purdue was "working with Practice Fusion to conduct a pilot (test) with Butrans advertising on the EHR (electronic health record) site to determine if banner ads work at driving traffic to our e-marketing collateral (websites, savings cards online, patient education downloads, etc.). The strongest interest is in seeing if we can improve coupon and co-pay program utilization."[254]

339. And as early as September 13, 2012, Ryan Howard [redacted]

[redacted]

[251] Ryan Howard, "How to Prevent Your Company from Being Used for Evil From a Founder Who's Been There," *Entrepreneur*, November 28, 2020, *available at*: https://www.entrepreneur.com/article/359624 (emphasis in original).
[252] Ryan Howard, "How to Prevent Your Company from Being Used for Evil From a Founder Who's Been There," *Entrepreneur*, November 28, 2020, *available at*: https://www.entrepreneur.com/article/359624
[253] Ryan Howard, "How to Prevent Your Company from Being Used for Evil From a Founder Who's Been There," *Entrepreneur*, November 28, 2020, *available at*: https://www.entrepreneur.com/article/359624
[254] PPLPC018000741102

[redacted][255]

340. Then, on February 25, 2014, [redacted][256]

341. In other words, [redacted] Howard wrote, "I was not part of any conversation with any opioid manufacturer while I was CEO."[257] [redacted] Maybe he forgot.[258] Howard's words of wisdom to other founders regarding preventing their companies being "used for evil" are heartfelt, nonetheless.

[255] PPLPC022000561019
[256] PPLPC021000631187
[257] Ryan Howard, "How to Prevent Your Company from Being Used for Evil From a Founder Who's Been There," *Entrepreneur*, November 28, 2020, *available at*: https://www.entrepreneur.com/article/359624

[258] Likewise, Howard may have forgotten [redacted] *See* MNK-71_0006314898; MNK-T1_0006316021.

342. On August 18, 2015, Ryan Howard stepped down from his role as CEO of Practice Fusion and became Chairman of the Board. The Chief Commercial Officer, Tom Langan, replaced Howard as CEO. Langan had joined Practice Fusion only one year before.[259]

343. Within months of Howard's departure, Practice Fusion hired JPMorgan Chase to explore the possibility of the company's initial public offering at a valuation range of $1.1 to $1.5 billion valuation in 2017. The valuation was based on projected annual revenues in 2018 of between $155 million and $181 million.[260] Its actual annual revenue in 2015, the year Practice Fusion engaged its financial advisors to explore sales options, was approximately $50 million.[261]

344. Around the same time, however, Practice Fusion was seeking other options. Practice Fusion's board hired Evercore, an investment bank, in November 2015 to solicit interest from people who might want to buy Practice Fusion whole. Interested parties indicated a bid range for Practice Fusion between $50 million to $225 million, a fraction of the IPO valuation.[262]

345. Four months after engaging Evercore and obtaining the low estimated offers, Practice Fusion was eager to show greater profitability as soon as possible so as to close the gap between the low valuations anticipated in a whole company sales transaction versus the billion dollar company it wanted to be in the event of an IPO.

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[259] Mark Sullivan, "Practice Fusion CEO Ryan Howard steps down, becomes chairman of the board," *Venture Beat*, August 18, 2015, *available at*: https://venturebeat.com/2015/08/18/practice-fusion-ceo-ryan-howard-steps-down-becomes-chairman-of-the-board/

[260] Katie Benner, "Practice Fusion Said to Hire JPMorgan Chase to Explore I.P.O.," *New York Times*, January 19, 2016, *available at*: https://www.nytimes.com/2016/01/20/business/dealbook/practice-fusion-said-to-hire-jpmorgan-chase-to-explore-ipo.html

[261] Christina Farr, "Employees at Practice Fusion expected IPO riches, but got nothing as execs pocketed millions," *CNBC*, January 23, 2018, *available at*: https://www.cnbc.com/2018/01/23/practice-fusion-workers-got-nothing-in-deal-as-execs-made-millions.html

[262] Christina Farr, "Employees at Practice Fusion expected IPO riches, but got nothing as execs pocketed millions," *CNBC*, January 23, 2018, *available at*: https://www.cnbc.com/2018/01/23/practice-fusion-workers-got-nothing-in-deal-as-execs-made-millions.html

346. In February 2016, Practice Fusion fired one quarter of its workforce. Howard's successor, Langan indicated the downsizing was necessary "to get the company to a profit, at the same time that the low-priced acquisition offers were starting to accumulate."[263]

347. It was within this context, with Practice Fusion desperately seeking near term revenue in order to validate an inflated valuation of the company, that Practice Fusion partnered with Purdue, who was likewise willing to pay top dollar in order to obtain its *own* "near term" growth. The two companies needed each other. For example, in discussing the proposed CDS alert program with Purdue, Practice Fusion's Senior Vice President on May 11, 2015, noted that there was "urgency" for Practice Fusion to generate revenue.[264]

348. Ultimately, Practice Fusion was sold to Allscripts, another EHR vendor, on January 8, 2018, for $100 million, more than 90% less than their projected IPO valuation, in "a disappointing fire sale."[265]

I. ZS – The Salesforce Specialists

349. Management consulting is the business of providing solutions to corporate clients. "Business consulting is really focused on solving our clients' business problems, and it is a very diverse set of issues that we might tackle, for example, 'where are the growth the growth opportunities in our business, and how to we go after them,' to something very specific, like 'what is the comp design that we should put together to incentivize our sales representatives next

[263] Christina Farr, "Employees at Practice Fusion expected IPO riches, but got nothing as execs pocketed millions," *CNBC*, January 23, 2018, *available at*: https://www.cnbc.com/2018/01/23/practice-fusion-workers-got-nothing-in-deal-as-execs-made-millions.html

[264] Practice Fusion Information at Para. 45.

[265] Christina Farr, "Practice Fusion, once headed for $1.5 billion valuation, ends in 'disappointing' fire sale," *CNBC*, January 8, 2018, *available at*: https://www.cnbc.com/2018/01/08/practice-fusion-acquired-by-allscripts-for-100-million-in-cash.html

quarter,'" explained Kelly Tousi, a Principal at ZS Associates.[266] "That's a wide range, as you can imagine, and we do everything in between," she said.[267]

350. Solutions take many forms, depending on and tailored to the client's needs. "Management consulting includes a broad range of activities, and the many firms and their members often define these practices quite differently."[268]

351. As described above, broadly speaking, there are two schools of management consulting, namely "Strategy Consulting" and "Implementation Consulting." ZS engages in both.

352. ZS describes itself as "a professional services firm that works side by side with companies to help develop and deliver products that drive customer value and company results."[269] "Impact where it matters," the ZS webpage declares.[270] ZS describes its impact as results, not just ideas. "That's why we partner with our clients from strategy to implementation and beyond."[271]

353. Consistent with the origins of ZS in academia, the company's initial focus was on building models that could be used by their clients to drive decision-making regarding salesforce structure and operations. As the founders explain, "early in our modeling careers in the 1970's, our thinking was centered on models, and we believed that the model was a large and prominent art of solving sales-resource-optimization problems."[272]

354. Like many consulting firms, ZS performs both strategy and implementation work for its clients. But what sets ZS apart is that it has developed a particular niche in offering these

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[266] *See* "Business Consulting at ZS: learn how ZS recruits and interviews talent," ZS Associates, March 16, 2018, *available at* https://www.youtube.com/watch?v=YZ3ZjARBnrI

[267] *Id*.

[268] Arthur Turner, *Consulting is More Than Giving Advice*, Harvard Business Review, September 1982, *available at*: https://hbr.org/1982/09/consulting-is-more-than-giving-advice.

[269] *See* https://twitter.com/ZSAssociates.

[270] *Id*.

[271] *See* https://www.zs.com/about/our-impact.

[272] *See* Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S35-36, May-June 2001.

services in the context of pharmaceutical sales and marketing. ZS specializes in the optimization of pharmaceutical sales forces in order to maximize sales and profit. In fact, ZS boasts that, "[i]n its first three years, ZS helped eight of the 10 largest pharmaceutical companies in the world align territories and resize their sales forces. By 2011, ZS worked with 40 of the 50 largest drug makers in healthcare and 17 of the 20 largest medical device makers."[273]

355. In addition to developing overall sales and marketing strategies for specific drugs and drug portfolios, ZS regards implementation work as a core component of its overall product offerings to its clients. Indeed, implementation – and in some instances wholesale outsourcing of key business functions to ZS – are included as a component of practically every project that ZS takes on for a client.

356. In the broadest of generalities, then, ZS' business model, as a provider of strategy and implementation consulting services to the pharmaceutical industry, is to partner with clients to pursue business objectives identified by ZS. Once the objective is identified, the client and ZS then engage in concerted action, as a seamless and cohesive unit, in order to implement the necessary means to achieve the objectives for the client.

357. Beyond these traditional consulting services, ZS Associates are also known to serve as thought leaders by authoring articles or providing soundbites or quotes in order to influence perceptions in their client's favor. For example, when physicians' offices began restricting access to sales representatives, ZS joined with manufacturers to create content designed to counter this movement.[274]

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[273] *See* https://www.zs.com/about/our-story.

[274] See George Chressanthis et. al., *Can Access Limits on Sales Representatives to Physicians Affect Clinical Prescription Decisions? A Study of Recent Events With Diabetes and Lipid Drugs*, The Journal of Clinical Hypertension, Vol. 14, No. 7, July 2012, *available at*: https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1751-7176.2012.00651.x

358. ZS optimizes pharmaceutical sales forces for the explicit purpose of increasing sales and profit for the manufacturer client. In 2001, the founders of ZS published a paper entitled "Sales-Force Decision Models: Insights from 25 Years of Implementation." Describing ZS specialist expertise, the founders stated, "Over 25 years, we have developed many sales-force and modeling insights through over 2,000 projects with several hundred selling organizations in over 50 countries … Two to three percent of all of the field salespeople in the US have been touched by the results. The firms had pressing issues that required quick attention. Companies sought help when merging separate selling organizations, when launching new products, when facing deregulation, or when faltering in performance."[275]

359. In 2013, Chris Wright, ZS' former Chief Executive Officer, explained to the *New York Times*: "There's a group of geeks, if you will, who are running the numbers and helping the sales guys be much more efficient."[276] The effect is "what would happen if Arthur Miller's Willy Loman met up with the data whizzes of Michael Lewis's 'Moneyball.'"[277]

360. Wright was only a managing director at ZS when he provided his comments to the *Times* in 2013. In his 25 years at ZS, according to an "Impact Fact" described on ZS' website, "Chris has helped dozens of pharmaceutical companies differentially resources their sales deployments, leading to multibillion-dollar industry cost savings."[278]

361. By exploiting "vast databases of patient and doctor information," companies like ZS can provide advanced analytics capabilities to clients to maximize sales efforts. "They know whether patients are filling their prescriptions – and refilling them on time. They know details of

[275] *Id.* at S9.
[276] Katie Thomas, "Pills Tracked from Doctor to Patient to Aid Drug Marketing," *New York Times*, May 16, 2013, *available at: https://www.nytimes.com/2013/05/17/business/a-data-trove-now-guides-drug-company-pitches.html*
[277] *Id.*
[278] *See* https://www.zs.com/about/our-people/Chris-Wright

patients' medical conditions and lab tests, and sometime even their age, income and ethnic backgrounds."[279]

362. ZS cannot drive customer value or company results, however, if its work is placed in a drawer and ignored. As such, ZS does not merely provide advice or models to clients. Instead, it works "side by side" with them to achieve results the client alone cannot. Implementation – that is, the continuation of working on a project for a client *after* ZS has provided advice or a proposal to the client and *after* the client has accepted the same – is a crucial component of ZS's work with its clients. This reality was recognized early on in the history of ZS. "Over the years, we have realized that we spend much more energy on other activities, such as articulating the issues, building databases, and dealing with change management and implementation. For example, in the geographic deployment work we have done, we spend over 95 percent of the time in activities *unrelated to model building*."[280]

363. Likewise, clients of ZS do not wish to pay top dollar for specialized management consulting services regarding their crucial sales and marketing practices merely for suggestions about how best to do things on their own. Just as an automobile manufacturer does not hire an airbag company to advise it on how to design, create, and install safe airbags in its cars, but instead just hires the airbag company to sell it safe airbags; pharmaceutical manufacturers hire consultants like ZS to implement mission-critical salesforce tasks they do not have the capability to perform on their own.

364. ZS explains on its website that it "implement[s] strategic decision for driving real change delivered at all levels by employing change management techniques based on human-

[279] Katie Thomas, "Pills Tracked from Doctor to Patient to Aid Drug Marketing," *New York Times*, May 16, 2013, *available at:* https://www.nytimes.com/2013/05/17/business/a-data-trove-now-guides-drug-company-pitches.html
[280] *Id.* at S36.

centered design principles."[281] Likewise, in its job listings, ZS explains that its employees will be involved in implementing the advice and recommendations provided by ZS when adopted by ZS' clients.[282]

365. ZS speaks in terms of "optimizing" its clients' efforts to sell its products. ZS' clients are for-profit companies, and "optimization" implies a specific variable you are optimizing. In the case of ZS, the variable is the amount of money the client can make.[283]

366. ZS applied its hard-won expertise to multiple clients, "optimizing" their salesforces for the purposes of maximizing the profits derived from selling controlled substances.

1. The Salesforce – Pharma's Engine

367. Sales forces are a major component of pharmaceutical companies' operations. Indeed, they are the core of the industry. In 2007, it was estimated that there were 100,000 pharmaceutical sales representatives in the United States pursuing approximately 200,000 prescribers.[284] In his 2015 deposition testimony, Richard Sackler agreed that "the main way [Purdue] marketed and promoted its OxyContin was with [Purdue's] salesforce."[285] Moreover, ZS explained to Endo that, with respect to its portfolio of pain medications, "sales force detailing is the most impactful tactic, detailing accounts for ~35-65% of all sales and marketing impact."[286]

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[281] *See* *https://www.zs.com/solutions/strategy-and-advisory/strategy-and-transformation*

[282] *See* https://jobs.zs.com/jobs/18188?lang=en-us (""We provide a complete spectrum of technology solutions, from strategy and roadmap definition to full scale implementation and on-going operations."); *see also* https://jobs.zs.com/jobs/16461?lang=en-us ("ZS's Business Technology Solutions team is responsible to lead end to end responsibility of project across all phases i.e. discovery, requirements gathering, design, implementation, testing and operations.")

[283] *See* https://www.zs.com/solutions/artificial-intelligence-and-analytics/analytics (Touting ZS's "Analytics optimization" solutions, ZS emphasized, "You need to ensure that you're investing in the right analytics capabilities, tapping into the right data sets and maximizing your ROI with key insights that drive business transformations.")

[284] Tobias L. Milrood, *When Drug Representatives Go Too Far*, American Association for Justice, February 2007.

[285] *See* Deposition of Richard Sackler, *available at*: https://www.youtube.com/watch?v=zUNrhPUV6Ew (at 4:21:43)

[286] Expert Report of Matthew Perri dated March 25, 2019, Doc 1908-37, *In re National Prescription Opiate Litigation*, Case No. 1:17-md-02804 (N.D. Oh.)(filed July 19, 2019), para. 59.

368. These armies of sales reps are employed by pharmaceutical companies and detailed to health care providers to market the companies' drugs to those with the power to prescribe them. By 2000, at the outset of the opioid crisis, pharmaceutical companies were spending in excess of $15 billion annually promoting drugs, with 84% of the total spend directed at detailing sales representatives to prescribers, drug samples, and ads in medical journals.[287]

369. "Because of the large size of pharmaceutical sales forces, the organization, management, and measurement of effectiveness of the sales force are significant business challenges."[288] This is ZS' niche. ZS tells its clients how to optimize, incentivize, and deploy these armies of pharmaceutical sales representatives for the purpose of maximizing revenue. In the words of ZS' founders, "[t]hat marketing investment drives sales is a fundamental principle supported by data."[289] ZS has observed the statistically significant relationship between sales force effort and sales of pharmaceuticals, as depicted in the following scatter plot[290]:

[287] M.B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers,* 346 New England J. Med. 498 (2002).
[288] Tobias L. Milrood, *When Drug Sales Representatives Go Too Far*, American Association for Justice, February 2007.
[289] Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S10, May-June 2001.*Id*. at S10.
[290] *Id.* at S12.

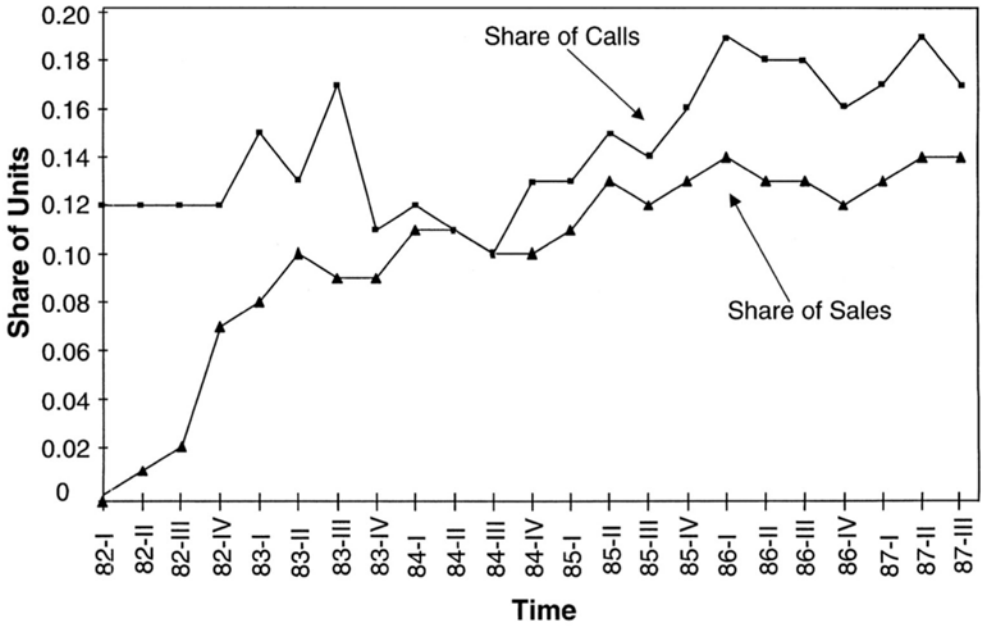

Figure 2: This scatter plot using longitudinal data shows a statistically significant relationship between sales-force effort and sales for a product sold by a pharmaceutical sales force. Every dot represents a quarter of the year.

370. ZS provided these services to numerous opioid manufacturers, which produced controlled substances known to be addictive at the time ZS advised them, for the explicit purpose of maximizing the sales and revenue of these deadly and addictive drugs during the pendency of a nationwide opioid crisis wrought by the over-selling of opioids by ZS' clients.

2. ZS – Pharma's long-term partner

371. Like many participants in the pharmaceutical consulting space, ZS does not merely provide advice to its clients on a one-off basis. Rather, according to ZS, a client relationship is "about results, not just ideas. That's why we partner with our clients from strategy to implementation and beyond."[291] "We work side-by-side with you at every stage to help you achieve success."[292] These partnerships are *long term*. For instance, ZS' founders have observed

[291] *See* https://www.zs.com/about/our-impact
[292] *Id.*

that, "having worked with some managers *repeatedly for over a decade or more*, we have observed patterns in the ways managers use consulting assistance and models."[293]

372. At ZS, "business consulting is really focused on solving our clients' business problems, and it is a very diverse set of issues that we might tackle, for example you could be anything from 'where are the growth opportunities in our business and how should we go after them,' to something very specific, like 'what is the comp design that we should put together to incentivize our sales representatives next quarter'? So that's a wide range, as you can imagine; we do everything in between."[294]

373. In other words, ZS does not merely provide ideas and advice to its clients. Rather, it designs and implements sales force models aimed at the most efficient allocation of marketing spending and maximization of profits for their manufacturer clients. In fact, ZS' recommendations are routinely implemented on such a systematic and industry-wide basis that ZS itself is now able to draw on its own history of implementing change for its clients, as a data set of its own worthy of academic study.[295]

3. ZS services its clients

374. Even though the marketing of OxyContin has been described as the "taproot" of the opioid epidemic, Purdue was not the only manufacturer to zealously market their own opioids. Nor was Purdue ZS' only opioid client.

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[293] Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S37, May-June 2001 (emphasis added).

[294] *See* ZS Associates, "Business consulting at ZS: learn how ZS recruits and interviews talent," *available at*: https://www.youtube.com/watch?v=YZ3ZjARBnrI. Incidentally, the factors ZS articulates in its sales pitch as firm competencies – identifying growth opportunities and incentivizing the sales representatives – are *both* identified as principal origin points of the opioid epidemic by Dr. Van Zee as early as 2002.

[295] Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S18-19, May-June 2001 ("The repeated application of several normative sales-force-decision models has produced a series of insights that have led to a number of valuable sales-force insights.")

375. ZS provided similar services, as explained below, to fellow opioid manufacturers Mallinckrodt Pharmaceuticals, Endo Pharmaceuticals, Teva Pharmaceuticals, and Johnson & Johnson's Janssen Pharmaceuticals. Consistent with its work for Purdue, ZS designed, implemented, and optimized salesforce strategies to maximize the profits derived from selling a controlled substance for practically every major opioid manufacturer. ZS' client work is described in individual detail below.

i. Purdue

376. As described above[296], after 2007 Purdue was pursuing the Sackler's goal of maximizing near-term OxyContin sales so as to extract as much money from Purdue as possible in order to diversify away from the dangerous "concentration of risk" that continued financial reliance on Purdue represented for the billionaire family.

377. ZS happily agreed to help, and by [redacted] ZS and Purdue were working together to increase sales of Purdue's opioids. [redacted] based on ZS' own independent research and unique methodologies, including modelling expertise. Purdue adopted ZS' strategies and worked closely with ZS to implement ZS' plan. Despite the strictures imposed upon Purdue by the Corporate Integrity Agreement, OxyContin sales began to multiply.

378. ZS' relationship with Purdue lasted at least through [redacted] during which ZS engaged in numerous projects for Purdue, each with the intent of maximizing sales and profits of Purdue's controlled substances.

[296] *See* Paragraphs 87-93, *supra*.

379. Purdue hired ZS for [redacted] These [redacted] were necessary in light of the Sackler family's – Purdue's sole owners – decision to exit the opioid business in light of the perceived risks of staying there.

380. From the outset, [redacted] – an acknowledgement by both Purdue and ZS of the real-world stakes at issue in ZS' work.

381. ZS' first known work for Purdue commenced in the final months of [redacted] and focused on [redacted] One of the [redacted] ZS observed, was [redacted] In other words, ZS would find ways to get prescribers to *change their prescribing behavior* by prescribing more extended-release opioids for longer periods of time.

382. Once ZS identified the drivers behind these prescriber behaviors, ZS developed a plan to "correct" the behavior in ways beneficial to Purdue, and, once adopted by the client, began implementing changes at Purdue to increase OxyContin sales. ZS would "evaluate and determine optimal sales and marketing strategy to support OxyContin," and would "draw an implementation roadmap" incorporating "tangible action steps regarding identified OxyContin hurdles in terms of sales, marketing, and managed care approach. ZS would also conduct "Solution Design Workshops" with Purdue's staff regarding the best ways to undertake the changes in strategy identified by ZS.

383. In [redacted] while Purdue was still bound by the Corporate Integrity

Agreement. This time ZS' work related to [redacted]

384. The work took a holistic approach to Purdue's entire sales and marketing efforts for its pain portfolio, including OxyContin, MS Contin, and RyzoltTM.

385. In addition to working on Purdue's existing pain portfolio, in [redacted] ZS assisted Purdue in [redacted] At that early point in the opioid crisis, Purdue was already interested in expanding into products for the treatment for opioid use disorder, which, according to ZS, [redacted]

386. ZS focused on answering mission-critical questions for Purdue, including but not limited to:

[redacted]

387. As always, ZS' work included an implementation component, including [redacted] and [redacted] ZS assured Purdue that [redacted]

388. In 2012, [redacted]

[redacted]

389. [redacted] ZS agreed to [redacted] and [redacted] ZS agreed to address "key questions" like [redacted] Additionally, ZS undertook an analysis to [redacted]

390. ZS conducted this work in conjunction with a core team of Purdue employees [redacted]

391. By 2013, one year after Purdue was no longer shackled by the constraints of the 2007 Corporate Integrity Agreement that expired in 2013, Purdue also engaged with a separate consulting company, McKinsey & Company, Inc., to design a new company-wide sales and marketing approach. McKinsey's proposals, initially dubbed *Project Turbocharge*, were eventually rechristened *Evolve to Excellence* and were implemented by McKinsey and Purdue for

the explicit purpose of maximizing opioid sales despite the by-then obvious risks associated with selling as much OxyContin as possible.

392. ZS worked in cooperation with McKinsey and Purdue to implement and continually refine *Project Turbocharge*, including [redacted] McKinsey's efforts to target the highest prescribers of OxyContin and blitz them with the newly turbocharged sales force. ZS worked with an Executive Oversight Team and Project Management Office, comprised of Purdue and McKinsey staff, to implement McKinsey's plans for Purdue.

393. That same year, despite significant headwinds, OxyContin sales finally peaked. The restrictions on Purdue's sales and marketing methods contained in the Corporate Integrity Agreement should have resulted in fewer overall OxyContin sales. Within five years of Purdue's guilty plea, however, OxyContin sales tripled.

394. ZS played a crucial role in accomplishing this feat. It presented specific plans to Purdue, which Purdue adopted and spent hundreds of millions of dollars implementing alongside ZS and other consultants. The result: a final spasm of OxyContin sales before the inevitable decline of the drug.[297]

395. In August of 2013, McKinsey urged, as part of the overall sales maximization approach, that sales representatives should devote two-thirds of their time to selling OxyContin and one-third of their time selling Butrans, another Purdue product. Previously, the split had been fifty-fifty.

396. Two months later, [redacted]. ZS sought to answer the question, [redacted]

[297] On February 10. 2018, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force.

[redacted] Within months of McKinsey's recommendation that Purdue should shift its resource allocation from a 50/50 split between OxyContin and Butrans to 2/3's OxyContin and 1/3 Butrans, [redacted]

397. In other words, [redacted] As stated earlier (and exemplified here), the pharmaceutical industry is complex, and manufacturers do not do everything themselves. Purdue continually sought the ongoing assistance of ZS and many others to achieve its aims.

398. In conjunction with the ongoing implementation of McKinsey's *Evolve to Excellence* at Purdue, ZS' relationship with Purdue flourished. With the rollout of *Evolve to Excellence* in 2014, ZS was intimately involved in Purdue's sales transformation. [redacted] The requests for support were granular in their detail, including a [redacted] and [redacted] which was work necessary to implement the overall physician targeting strategy espoused and directed by McKinsey at Purdue, such as the design of a [redacted]

399. ZS was not merely working on a project that McKinsey created and oversaw. ZS routinely interacted with McKinsey consultants in furtherance of their mutual goal of maximizing sales of Purdue's opioids. For example, on July 31, 2013, [redacted][298] A few weeks later, [redacted][299] Then, on October 15, 2013, [redacted].[300] At the same meeting, [redacted][301] Two weeks later, [redacted]"[302] [redacted]"[303]

400. The following month, the Project Management Office recommended to the Executive Oversight Team through which McKinsey and Purdue implemented E2E [redacted][304]

[298] MCK-MDL1996-0219810
[299] MCK-MDL2996-0220115
[300] MCK-MDL2996-0077806
[301] MCK-MDL2996-0077806
[302] MCK-MDL2996-0077733
[303] *Id.*
[304] MCK-MDL2996-0421514

[redacted] the email stated.[305]

401. Throughout this time period, [redacted][306]

402. By this time, ZS had also begun providing its AccessMonitor software for Purdue to use. AccessMonitor is one example of a common tactic used by consultants to maintain an ongoing revenue stream from its clients, separate and apart from traditional project-based work: the development and marketing of "leave-behind" products, such as software applications, that are sold to clients as tools that can be used by the business on an on-going and recurring basis, separate and apart from the project-based consulting work that is ZS' core offering.

403. As described by famed Harvard Business School Professor Clayton Christensen, these sorts of "software and technology-based analytics and tools that can be embedded at a client," are a tool used by a consultancy to deepen its partnerships with clients and earn additional and recurring revenue from them. Tools such as ZS' AccessMonitor, Prof. Christensen noted, provide "ongoing engagement outside the traditional project-based model" traditionally used by consultants.[307]

404. By 2017, McKinsey was working on Project Scottsdale for Purdue. The goal of the project was to "transform Purdue's entire business model" by splitting Purdue's assets into three

[305] *Id.* (emphasis added).
[306] MCK-MDL2996-0326142 (emphasis added).
[307] Clayton Christensen, Dina Wang, and Derek van Bever, "Consulting on the Cusp of Disruption," *Harvard Business Review*, October 2013, *available at* https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption

separate companies and downsizing the employee headcount at the companies by 500 people.[308] Just like Project Turbocharge, ZS collaborated with McKinsey on Project Scottsdale. In a December 2017 internal McKinsey email, McKinsey consultant Albert Lee reported to John Goldie and Amir Golan that work on re-sizing Purdue's sales forces pursuant to the goals of Project Scottsdale was "a WIP [work in progress] with ZS."[309]

405. In December of 2015, ZS' client Purdue agreed to a settlement with the State of Kentucky relating to the improper marketing of OxyContin and other Purdue products. Purdue agreed to pay $24 million in conjunction with the settlement.

406. Despite this second enforcement action against its client, ZS' work on Purdue's sales and marketing efforts continued unabated. Throughout its relationship with Purdue, ZS worked on core functions of Purdue's efforts to sell its drugs.

407. These core functions were previously identified as particular areas of concern with respect to Purdue's business conduct, and were specifically monitored and regulated under the 2007 Corporate Integrity Agreement, which governed, *inter alia*:

- "selling, marketing, promoting, advertising, and disseminating Materials or information about Purdue's products in compliance with all applicable FDA requirements, including requirements relating to the dissemination of information that is fair and accurate … including, but not limited to information concerning the withdrawal, drug tolerance, drug addiction or drug abuse of Purdue's products;

- compensation (including salaries and bonuses) for Relevant Covered Persons engaged in promoting and selling Purdue's products that are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion or sales of Purdue's products; …

[308] The Firm and the FDA: McKinsey & Company's Conflicts of Interest at the Heart of the Opioid Epidemic, Interim Majority Staff Report, Committee on Oversight and Reform, U.S. House of Representatives, April 13, 2022, at Pg. 27, *available at*: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2022-04-13.McKinsey%20Opioid%20Conflicts%20Majority%20Staff%20Report%20FINAL.pdf

[309] MCK-MDL2996-0334687

- the process by which and standards according to which Purdue sales representatives provide Materials or respond to requests from HCP's [health care providers] for information about Purdue's products, including information concerning withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products," including "the form and content of Materials disseminated by sales representatives," and "the internal review process for the Materials and information disseminated by sales representatives."[310]

408. In fact, under the terms of Paragraph II.C.1(b) of the Corporate Integrity Agreement, ZS, as a contractor to Purdue performing sales and marketing functions for the company, was a "Covered Person" subject to the strictures of the CIA.[311]

409. In addition to ZS' "expertise and thought leadership," ZS' assumption of these obligations for Purdue involved the deployment of Javelin, its proprietary salesforce optimization software tool. Like AccessMonitor, described *supra*, Javelin was a software tool that ZS could embed with clients. With Javelin, a ZS client can "streamline sales performance management with a comprehensive platform that simplifies sales strategy management and helps you build and motivate a successful sales force."[312] The Javelin products include "suites" of software for the management and operation of Incentive Compensation (IC) and Call Planning (CP) functions.[313]

410. Upon information and belief, all of Purdue's then 712 sales representatives were licensed users of ZS' trademarked Javelin suite of software solutions.

411. On October 20, 2020, Purdue entered into a plea agreement with the United States Department of Justice to plead guilty to improper marketing of OxyContin and other opioids,

[310] *See* https://s3.documentcloud.org/documents/6452110/2007-Purdue-Corporate-Integrity-Agreement.pdf at pgs. 7-9.
[311] The relevant language in the CIA provides: "'Covered Persons' includes … all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions … on behalf of Purdue." *Id.* at 2.
[312] *See* https://www.zs.com/products/javelin.
[313] *Id.*

again.[314] This time the plea agreement concerned conduct from 2010 to 2018. ZS collaborated with Purdue on its sales and marketing practices [redacted] the time period relevant to Purdue's second guilty plea.[315]

412. Purdue agreed to plead guilty to a dual-object conspiracy to defraud the United States and violating the Food, Drug, and Cosmetic Act, 21 U.S.C. § 331, 353, among other charges, relating to its opioid sales and marketing practices after the 2007 guilty plea.[316] Purdue's co-conspirators were not identified in the plea agreement.

413. Purdue's second guilty plea concerns Covered Conduct (as defined in the plea agreement) relating to Purdue's sales and marketing efforts that directly implicates ZS in the conspiracy. ZS' work for Purdue described in this Complaint was a core component of the sales and marketing tactics that lead to Purdue's second guilty plea.

ii. Mallinckrodt

414. Upon information and belief, around the same time ZS was working with Purdue to implement McKinsey's *Project Turbocharge* to maximize OxyContin sales by continual refinement of physician targeting and other sales and marketing tactics, ZS was also working with another long-term client, Mallinckrodt, [redacted]

415. Mallinckrodt is the largest supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States. In 2015, for instance,

[314] *See* https://www.justice.gov/opa/press-release/file/1329576/download

[315] On February 10, 2018, [redacted] Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force. "OxyContin maker stops promoting opioids, cuts sales staff," *Reuters*, February 10, 2018, *available at*: https://www.reuters.com/article/us-usa-opioids-purduepharma/oxycontin-maker-stops-promoting-opioids-cuts-sales-staff-idUSKBN1FU0YL ("OxyContin maker Purdue Pharma LP said on Saturday that it has cut its sales force in half and will stop promoting opioids to physicians, following widespread criticism of the ways that drugmakers market addictive painkillers."). As such, ZS [redacted]

[316] *See https://www.justice.gov/opa/press-release/file/1329576/download*

Mallinckrodt's opioids accounted for approximately one quarter (25%) of the entire annual production quota for controlled substances under DEA regulations. Mallinckrodt produced the following branded and generic opioids:

Product Name	Chemical Name
Exalgo	Hydromorphone hydrochloride, extended release
Xartemis XR[104]	Oxycodone hydrochloride and acetaminophen (extended release)
Roxicodone[105]	Oxycodone hydrochloride
Generic	Oxymorphone hydrochloride (extended release) (generic Opana)
Generic	Oxycodone (extended release) (generic OxyContin)
Generic	Morphine sulfate, extended release
Generic	Morphine sulfate oral solution
Generic	Oxycodone and acetaminophen (Percocet)
Generic	Hydrocodone bitartrate and acetaminophen (Vicodin)
Generic	Hydromorphone hydrochloride
Generic	Hydromorphone hydrochloride, extended release (Generic Exalgo)
Generic	Fentanyl transdermal system
Generic	Oral transmucosal fentanyl citrate
Methadose	Methadone hydrochloride
Generic	Methadone hydrochloride
Generic	Buprenorphine and naloxone

416. Previously, [redacted] Mallinckrodt sought to use ZS' expertise to [redacted] and to [redacted]

417. Mallinckrodt promoted Exalgo as having characteristics that made the drug less likely to be addictive or abused, despite the lack of FDA approval for the drug as "abuse-deterrent."

418. Then, on March 12, 2014, Mallinckrodt obtained FDA approval for Xartemis XR, its extended-release opioid tablet.[317] Upon information and belief, by the time Mallinckrodt

[317] *See* "Xartemis receives approval: May reduce opioid abuse," Formulary Watch, March 28, 2014, *available at* https://www.formularywatch.com/view/xartemis-xr-receives-fda-approval-may-reduce-opioid-abuse

obtained approval to market its opioid, ZS had already established a long-term working relationship with Mallinckrodt regarding the sales and marketing of Mallinckrodt's portfolio of pain medications.

419. ZS was intimately involved [redacted] from the outset.

420. In anticipation of Xartemis' launch, Mallinckrodt augmented its salesforce by adding hundreds of contracted sales representatives to promote the drug. CEO Mark Trudeau anticipated Xartemis would generate "hundreds of millions" in revenue for Mallinckrodt.[318]

421. In September, only months after FDA approval, ZS unveiled an overall sales and marketing strategy for the drug. The scope of the plan was all-encompassing, including overall global strategy as well as granular details of execution and implementation. Tactics to be deployed in ZS' plan included the deployment of marketing materials in the offices of health care providers (including "in-office patient education materials" meant for the consuming public), physician targeting and decile segmentation, a video series interviewing clinicians about the benefits of the drug, patient testimonials, a speaker program, patient co-pay cards, targeting promotion outreach to regional associations of physician assistants[319], and other efforts to maximize sales and revenue. Many of these same tactics were weapons in Purdue's arsenal, designed by ZS.

422. Part of ZS' plan [redacted]

[redacted]

[318] *See* https://www.bizjournals.com/stlouis/blog/health-care/2014/01/mallinckrodts-new-drug-should.html

[319] This focus on physician's assistants is consistent with ZS' finding in an August 2016 report it issued, arguing that "[a]nother way to increase reps' chances for success is to expand the potential audience beyond the physician." ZS explained, "Other people on staff at the physician's office could be worthwhile targets for pharmaceutical messaging, such as nurse practitioners and physician assistants. *On average, people in these roles are incrementally more accessible than physicians.*" *Physicians Becoming More Restrictive About Rep Sales Calls; Digital Communications Picks Up*, 28 No. 8 FDA Advertising & Promotion Manual News. 8, October 2016 (emphasis added).

[320] "TRx" is an abbreviation for the measurement of increase in "total prescriptions," meaning all new prescriptions **plus** refills on those prescriptions. "Growing TRx," in other words, means encouraging refills of new prescriptions. This approach to maximizing revenue by encouraging refills of controlled substances known to be addictive carried obvious risks.

[redacted] in addition to [redacted]

423. ZS' [redacted]

424. Ominously, [redacted]

425. Mallinckrodt encouraged its sales reps to aggressively market its new opioid by implementing ZS' marketing and sales strategy. One supervisor urged the Xartemis sales force to "ATTACK" health care providers and informed representatives that they could obtain "big bonus dollars" by waiting in front of doors of health care providers and using free trial offers to gain prescriptions.[321]

426. Another sales supervisor encouraged sales representatives that Xartemis "is the BEST opportunity to make lots of money!!!"[322]

427. ZS designed and implemented the incentive compensation plan for Xartemis.

[321] William K. Rashbaum, Roni Caryn Rabin and Danny Hakim, "Opioid Sales Reps Swarmed New York at Height of Crisis," *New York Times*, April 19, 2019, *available at* https://www.nytimes.com/2019/04/11/health/opioids-sacklers-new-york-purdue.html

[322] *Id*.

428. The above is even more alarming in light of the fact that ZS had been using its hub-like position among many manufacturers to develop a business intelligence tool by analyzing call note reports from over 45,000 sales reps across the country.[323] Given their ability to analyze the large amounts of data ZS possessed, ZS were the only ones with the keys to unlock the prescribing practices of each target physician.

429. Mallinckrodt repeatedly promoted Xartemis ZR as having physical properties that made the drug less likely to be addictive or abused, even though the drugs had never been approved by the FDA as abuse-deterrent. For instance, promotional materials provided to prescribers stated "Xartemis XR has technology that requires abuses to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[324]

430. Not only had the FDA not approved Xartemis as an abuse-deterrent formulation, the marketing claims were false and misleading in that none of the characteristics of Xartemis address the most common form of opioid abuse: simple oral ingestion, swallowing the pill.

431. As stated above, the data and analytics capabilities of ZS, when tasked to the purpose of maximizing drug sales and revenue, should result in the unearthing of suspicious orders worthy of reporting to the DEA.[325] Despite ZS working with Endo to assiduously study in granular detail the topic of where its pills are sold (and how to sell more of them), Endo nonetheless failed in its reporting obligations under the Controlled Substances Act.

432. In a July 2017 Memorandum of Agreement with the DEA and the Department of Justice, Mallinckrodt agreed that "at certain times during the Covered Time Period prior to January

[323] See "Crossing the threshold: More than half of physicians restrict access to sales reps," *ZS Associates*, September 1, 2015, *available at*: https://www.zs.com/about/newsroom/crossing-the-threshold-more-than-half-of-physicians-restrict-access-to-sales-reps

[324] *See* "Xartemis receives approval: May reduce opioid abuse," *Formulary Watch*, March 28, 2014, *available at* https://www.formularywatch.com/view/xartemis-xr-receives-fda-approval-may-reduce-opioid-abuse

[325] *See supra,* ¶ 64-65.

1, 2012, certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control to registrants [Mallinckrodt] dated September 27, 2006, and December 27, 2007."[326]

iii. Endo

433. ZS' relationship with Endo Pharmaceuticals [redacted]

434. Upon information and belief, [redacted] months after Endo's launch of Opana ER, its extended-release oxymorphone tablet in 2006. At the time, Endo's marketing efforts were primarily focused on Opana ER, its branded extended-release oxymorphone hydrochloride tablet. Oxymorphone hydrochloride is three times as strong as morphine.

435. ZS' first known work for Endo involved developing and implementing [redacted] ZS acknowledged.

436. ZS designed [redacted] for Opana. This was crucial, as Endo required a [redacted] in order for Endo to [redacted]

437. Moreover, ZS was engaged not only [redacted]

[326] *See* the July 2012 Memorandum of Agreement between Mallinckrodt and the DEA at https://www.justice.gov/usao-edmi/press-release/file/986026/download

438. By 2009, [redacted] As such, ZS was tasked with [redacted]

439. ZS' focus on ROI for its clients, described in Section D, above, is front and center in the title of its July 16, 2012, presentation to Endo Pharmaceuticals: "Promotional Mix Optimization Brand Level Model Results and ROI." In it, ZS conducted a "historical ROI and marginal ROI analysis" of Endo's "pain brands." As explained in the presentation, at the time Endo had been employing "a variety of marketing tactics to **drive prescribing volume** within the Pain and UEO portfolios," and Endo "would like to better understand the effectiveness of each of these tactics, and to **optimize marketing spending to drive efficiency**."[327] Key questions ZS sought to answer for its client were "how effective is each of Endo's marketing activities in terms of driving prescription volume," and "what is the ROI for each marketing activity."[328]

440. ZS informed Endo plainly that, regarding its portfolio of pain medications, "[s]ales force detailing is the most impactful tactic, detailing accounts for 35-65 & of all sales and marketing impact."[329] With respect to Opana, Endo's extended-release opioid tablet meant to compete with Purdue's OxyContin, sales force detailing accounted for 11.7% of the contribution

[327] ZS Presentation to Endo dated July 16, 2012, *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP, Doc. 2421-2, filed August 15, 2019 (N.D. OH).
[328] *Id.*
[329] *Id*.

to annual sales and profitability among Endo's sales tactics for Opana. In second place was co-pay cards, with 4.4%:[330]

% Contribution to annual sales and profitability by promotional tactic for each brand

Modeling time frame	Apr'11- Mar'12	Jan'11- Dec'11		Apr'11- Mar'12
Tactic	LIDODERM	OPANA	Voltaren Gel	FROVA
SF Detailing	8.3%	11.7%	5.9%	8.2%
NPP	3.1%	0.0%*	3.5%	7.5%
Samples	5.0%	N/A	2.1%	1.0%
Website	2.0%	2.1%	0.0%*	0.1%
Journals	0.5%	0.3%	N/A	N/A
Copay cards	0.4%	4.4%	2.7%	6.4%
Speaker programs	Not planned for 2012	0.2%	N/A	N/A
ALL TACTICS	19.3%	18.7%	13.2%	23.2%
CARRYOVER	77.1%	73.4%	70.8%	45.2%
OTHER FACTORS	3.6%	7.9%	15.0%	31.6%

Positive mROI
Approximately Breakeven mROI
Negative mROI

** Not a statistically significant impact*

)12 ZS Associates – 9 – 2012_07_16 Promo Mix Optimization - ROI analysis v*

441. Opana ER constituted $383 million in annual sales for Endo at the time of the ZS Associates analysis, good enough for the second highest selling Endo product analyzed by ZS. Of that $383 million in sales, ZS determined that 19%, or $72 million, is "driven by Sales and Marketing."[331] Furthermore, ZS informed Endo that "most of the promotional channels for Opana ER have high ROI." These "promotional channels" include marketing tactics such as copay cards, website advertising, medical journal sponsorship, speaker programs, and detailing to prescribers.

442. The Opana marketing messages whose delivery ZS sought to optimize for Endo conveyed misrepresentations regarding the dangers of the drug. For example, Endo maintained

[330] *Id.*
[331] *Id.*

until April 2012 the website opana.com, which stated, "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." Upon information and belief, Endo did not conduct and does not possess data or evidence to support that statement. Furthermore, the statement is misleading in that it suggests that addiction is not a risk from taking extended-release opioids such as Opana.

443. Thus, ZS worked with Endo for at least a decade optimizing and implementing misleading sales and marketing tactics, *including managing critical sales and marketing functions* such as IC and CP. ZS' successful performance of these tasks was critical to Endo's efforts to market Opana. Without ZS, Endo could not have achieved its opioid revenue goals.

444. On March 3, 2016, the New York Attorney General announced a settlement with Endo to address the misleading marketing of Opana. The settlement required Endo "to cease all misrepresentations regarding properties of Opana ER, to describe accurately the risk of addiction to Opana ER, and to summarize studies regarding Opana ER on its website."[332] The settlement further required Endo to create programs to prevent its sales representatives "from promoting [Opana ER] to health care providers who may be involved in the abuse and illegal diversion of opioids."[333] Those safeguards were not in place under the sales and marketing program ZS designed and helped Endo implement for years. Even at the time of the settlement announcement, ZS was still working with Endo to shape and manage its Opana ER sales force.

445. In May 2017, an advisory committee to the Food and Drug Administration recommended that Opana ER be withdrawn from the market due in part to the fact Opana ER could be "readily prepared for injection" (thereby bypassing the purportedly "abuse-deterrent" features of the formulation that Endo touted in its marketing) and was associated with outbreaks of HIV

[332] *See* https://ag.ny.gov/press-release/2016/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo
[333] *Id.*

and a blood-clotting disorder known as thrombotic thrombocytopenic purpura ("TTP"). On June 8, 2017, the FDA adopted the committee's recommendation.[334]

446. One month later, on July 6, 2017, Endo announced that it would agree to cease marketing and selling Opana ER altogether.

447. Just as was the case with Purdue, ZS was working with Endo on marketing its branded opioid product at the time that the company voluntarily ceased selling and marketing the drug in response to the dangers of continuing to market it.

iv. Teva

448. Not to be left out, Teva Pharmaceuticals also relied on ZS [redacted][335]

449. Fentora is a fentanyl buccal tablet that is "used for the treatment of breakthrough pain in cancer patients receiving opioid treatment and who have become tolerant to it."[336] It was approved by the Food and Drug Administration in 2006 for this limited use, but, as the FDA noted two years later, "off-label prescribing has, unfortunately, been widely practiced."[337]

450. The Food and Drug Administration, in an April 26, 2008, memorandum discussing the possibility of an "expanded indication for Fentora for use in break-through pain in patients with chronic pain not caused by malignancy," expressed concern about Fentora's active ingredient,

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[334] "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, *available at*: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm

[335] *See* Teva Completes Acquisition of Cephalon, Fierce Pharma, October 11, 2011, *available at*: https://www.fiercepharma.com/pharma/teva-completes-acquisition-of-cephalon

[336] *See* Fentanyl Buccal Tablets (marketed as Fentora) Information, *available* at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fentanyl-buccal-tablets-marketed-fentora-information.

[337] Memorandum from Bob A. Rappaport, MD to the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) dated April 26, 2008, Doc. 2231, *In re National Prescription Opiate Litigation*, No. 1:17-md-02804-DAP (N.D. Ohio) (filed August 13, 2019).

fentanyl, and the growing misuse of opioids despite the safeguards already put in place by the FDA:

> Fentanyl has an extremely narrow therapeutic window, and even in opioid tolerant patients misuse and errors in dosing can result in significant morbidity and mortality. Exposure to minute quantities of fentanyl in opioid non-tolerant people, especially children and the elderly, can be lethal in minutes. If this product is to be indicated for increased widespread use, and if availability increases, a risk mitigation program that will attempt to prevent, monitor, and intervene, when necessary, will be essential. However, as already noted, *the current paradigms for risk management for potent opioid drug products may not have been fully successful*.[338]

451. Consistent with Dr. Rappaport's concerns, on December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for Fentora and other Transmucosal Immediate Release Fentanyl ("TIRF").[339]

452. The following year, ZS determined that [redacted]

453. [redacted]

[338] Memorandum from Bob A. Rappaport, MD to the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) dated April 26, 2008, Doc. 2231, *In re National Prescription Opiate Litigation*, No. 1:17-md-02804-DAP (N.D. Ohio) (filed August 13, 2019) (emphasis added).

[339] *See* https://www.fda.gov/drugs/information-drug-class/questions-and-answers-fda-approves-class-risk-evaluation-and-mitigation-strategy-rems-transmucosal.

[redacted][341].

454. [redacted]

455. ZS was tasked not only with specific recommendations to [redacted], such as [redacted], but in [redacted][342].

[340] *See* Corporate Integrity Agreement dated September 28, 2008, *available at*: https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf

[341] *See* Corporate Integrity Agreement dated September 28, 2008, *available at*: https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf

[342] The concept of "marketing mix" is one used by ZS to contextualize the product offerings it provides clients. "Marketing mix, simply stated is really just the set of promotional tactics that a product is using to sell and market itself. In the pharmaceutical industry, this can include a broad set of different kinds of promotional activities, things from very traditional tactics such as salesforce promotion or sampling, to more recent advances, things like co-pay cards, digital media," explained ZS' John Bienko. "Of course, the biggest question on anybody's mind is 'what is the financial impact I'm getting from these promotions, what's the bang for the buck?,'" he added. *See* https://www.youtube.com/watch?v=V8mppVKr9_0

Obtaining an optimal marketing mix is an overarching goal of any client relationship ZS maintains. For example, in addition to its work for Teva, the concept of marketing mix was front of mind for ZS' work for Endo as well. *See supra, Paragraph 869*. "Optimal," in this context, means most profitable.

456. In short, ZS was in charge of maximizing Teva's profit from selling fentanyl by optimizing and assisting in managing Teva's sales force.

v. Johnson & Johnson/Janssen

457. In addition to the manufacturer clients described above, ZS also worked for Janssen Pharmaceuticals, Johnson & Johnson's subsidiary that sold opioids. [redacted] Johnson & Johnson used ZS just like everyone else: always.

458. In September 2003, ZS assisted Janssen in expanding the marketing of Duragesic, Janssen's fentanyl patch, beyond the cancer patients for whom the drug was indicated. ZS identified "a significant opportunity for greater Duragesic usage for applications outside of cancer pain, especially back pain."[343]

459. "Moving back pain from an opportunity area to a core application is an important objective for the brand," ZS explained of the fentanyl product. "Similar opportunities [to sell fentanyl] may be present in fibromyalgia, arthritis and neuropathic pain," ZS explained.[344]

460. Accordingly, ZS suggested that Janssen's sales force undergo "[a] shift in targeting and detailing frequency from Oncologists to PCPs and Pain Specialists may be required to drive greater consideration of Duragesic for these applications."[345]

461. The September 2003 study by ZS also made use of sales data from IMS Health to indicate that "Duragesic continues to gain share from OxyContin," and moreover that "abuse potential is the main reason for decreasing OxyContin." Not only does this indicate ZS' knowledge *as early as 2003* that OxyContin (which ZS *also* helped sell) was being abused, but that that abuse

[343] Expert Report of David Kessler, Doc. 1927-3, *In re National Prescription Opiate Litigation*, Case No. 1:17-md-02804 (N.D. Oh. July 19, 2019).
[344] *Id.*
[345] *Id.*

liability could misleadingly be utilized as a point of *product differentiation*: the notion that the fentanyl patch was less addictive than the oxycodone pill. "[L]ower abuse potential and fewer peaks and troughs are the most commonly cited reasons for increasing prescribing of Duragesic," ZS said. Accordingly, "efforts to foster awareness of abuse issues may help accelerate and maintain the shift to Duragesic." But there was some risk is arguing that one opioid is more or less addictive than the other: these efforts "must be carefully designed to minimize negative effects *on the class as a whole*."[346]

462. The foregoing paragraphs make clear ZS' central role in the operations of its clients. Just as all pharmaceutical companies rely on IMS Health for sales data, or McKinsey for strategy consulting, practically *all* opioid manufacturers depend on ZS for salesforce optimization and sales and marketing advice. ZS is a critical part of the economic ecosystem that sells drugs in the United States.

J. Defendants' work kills people.

463. For Defendants, the name of the game is pleasing clients. Client retention is a key metric by which publicly traded advertising firms like Publicis and Allscripts are judged in the capital markets and therefore pay particular attention to. Client retention ensures stable revenue streams for agencies like the Big Four, which is seen as more valuable in the eyes of capital markets than one-off engagements. At the same time, Defendants must exert effort (which costs money) to retain a new client. Client development is a *cost* for Defendants, and selling additional services to an existing client is an inexpensive way to maximize the return on the investment ("ROI") that Defendants make in developing and maintaining a client relationship.

[346] *Id*. (emphasis added).

1. ROI is King

464. Likewise, from the client's perspective, return on investment is the coin of the realm as well. The profit motive drives behavior on both sides. If an agency does not increase revenue and profit for the client, they are worthless.

465. The only thing that matters is the bottom dollar, and the bottom dollar is driven by the volume of goods sold.

466. Publicis understands this. In Publicis' own words:[347]

> In healthcare, performance cannot be measured in clicks or impressions or even office visits. Our only KPI is outcomes — business outcomes and patient outcomes. Our best-in-class outcomes analytics methodology enables us **to see real ROI**. But sound, evidence-based measurement isn't just about **proving** ROI — it's also about **optimizing** for it. With the best data-driven analytics team in healthcare media, we're able to achieve performance that outclasses the field — with **ROI four times greater than our closest competitor.**

467. Publicis' actions for its clients provide numerous real-world instances of this myopic focus on money. For example, in April 2013, Publicis implemented an email marketing campaign offering downloadable OxyContin "Savings Cards," which Publicis knew was a tactic for patient retention, or, keeping patients on OxyContin for longer periods of time. Again, Publicis couched the campaign's worth in terms of "return on investment" for Purdue. While Publicis charged Purdue $47k for the campaign, Publicis and Purdue later assessed the incremental impact of the campaign to have been an additional 67,000 OxyContin prescriptions by April 2014.

468. Despite that apparent success, Publicis and Purdue wanted more. Notes from an internal Publicis meeting held four months later, in August of 2014, to discuss work on the Purdue account make it plain. Patient retention and return on investment remained top of mind:

[347] *See* https://www.publicishealthmedia.com/our-approach/ (emphasis added).

- Patient Retention – "How do we get a 2:1 return on this?"
  - What is a patient worth?
  - What is a monthly script worth?
  - What is the value of getting just *one* more refill?
  - Isn't brand retention so much as overall portfolio retention
- In the beginning, Purdue got reprimanded for going after patients too aggressively
- Hence the focus is more company versus brand oriented; feels more altruistic
- Determine at the patient level what they need for their condition
- Does portfolio retention need to be veiled in a patient engagement program?

"What is a patient worth?... How do we get a 2:1 return on this?... getting just *one* more refill." Internally, Publicis was direct in describing what matters.

469. The meeting was held to discuss additional projects to be performed in the realm of "patient retention" for Purdue. "Patient retention" for Purdue has all of the same benefits as "client retention" does for Publicis. In other words, Publicis was working to assure people stayed on their OxyContin prescriptions and never quit. Given the unpleasantness of that goal, Publicis wondered, "Does portfolio retention need to be veiled in a patient engagement program?"[348]

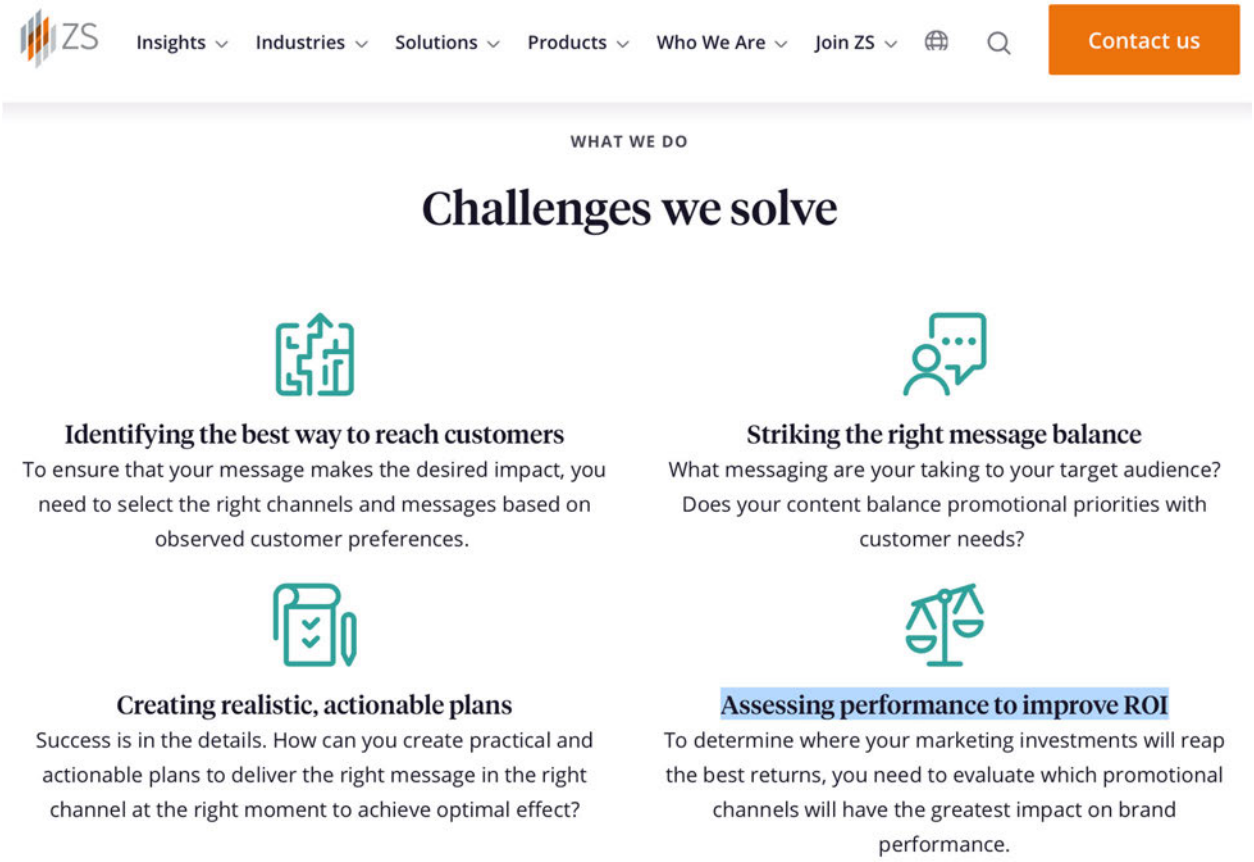
470. Likewise, ROI was paramount in Publicis' decision to engage Practice Fusion on the Purdue account. In a July 18, 2014, internal email, Publicis' John Dwyer asked a colleague, "Can you find out if they [Practice Fusion] have any kind of ROI of Rx impact metrics around these that they can share?"

471. ROI was king, but Publicis knew you couldn't just *say* that. In October 2014, Publicis was working with Purdue to devise an "Outward Facing Strategy," whereby Publicis would help Purdue present itself as a responsible corporate citizen to the world. Publicis noted that the current corporate tagline of "profitable growth" was not "outward facing" and was instead "strictly for internal use."

[348] For a discussion of why Publicis might wish to "veil" its retention goals in the guise of "patient engagement," *see supra* Section IV(e)(iii)(c).

472. Describing the bottom line regarding the services ZS provides its clients, ZS Principal John Bienko stated, "Of course, the biggest question on anybody's mind is 'what is the financial impact I'm getting from these promotions, what's the bang for the buck?'"[349]

473. ZS' *raison d'etre* is maximizing return on investment for all sales and marketing spending for a pharmaceutical manufacturer. ZS was not shy about couching its entire product line to pharmaceutical manufacturer clients in terms of ROI[350]:



474. ROI is the basis upon which ZS advertises and sells its services to pharmaceutical companies, and it is the principal reason that a pharmaceutical company hires ZS in the first place.

[349] *See* ZS Associates, "Marketing mix strategy: why it's so important for pharmaceutical marketing," available at: *https://www.youtube.com/watch?v=V8mppVKr9_0*
[350] *See* https://www.zs.com/solutions/marketing/promotions-and-marketing-mix

Matthew Day, Teva's Director of Marketing, explained: "ROI is return on investment. That is something that ZS Associates calculates on a sales call and whether or not it was effective."[351]

475. As established herein, ZS couched substantially *all* of its proposals to work for opioid manufacturers in terms of how much money they will make by doing what ZS recommends.

476. This myopic focus on the bottom line, when applied to controlled substances known to be addictive, would have predictable consequences.

2. Publicis Knew; Practice Fusion Knew; ZS Knew; Everyone Knew

477. As described above, the problem with broadly and aggressively marketing addictive opioids was apparent from the start: controlled substances are *controlled* precisely because they should not be sold to maximize volume and profits. Defendants actively disregarded this plain fact, repeatedly, and for decades.

i. Publicis Knew

478. Like Publicis Touchpoint Solutions' work with Orexo, Publicis's Saatchi and Saatchi also worked the other end of the epidemic. In 2017, it sponsored New York Festivals Global Awards Young Globals competition, where the winning team would win an internship opportunity. The Young Globals is "the only college/portfolio competition for healthcare advertising."[352] The competition called for "creative challenge briefs" to be submitted "for the (fictional) National Opioid Addiction Prevention Council and invites student entrants to develop a unique and compelling multi-channel experience (print, social media, digital, etc.) for their project Push Back on Opioid Abuse," in order to "raise awareness about opioid addiction."[353]

[351] Deposition of Matthew Day, Doc. 1976-11, *In re National Prescription Opiate Litigation*, Case No. 1:17-md-02804 (N.D. Oh.)(filed July 24, 2019), Pg. 204.
[352] *See* https://www.lbbonline.com/news/new-york-festivals-young-global-awards-open-for-entries
[353] *See* *https://www.lbbonline.com/news/new-york-festivals-young-global-awards-open-for-entries*

479. The same year, the President of the United States declared the opioid crisis a National Health Emergency.

480. Of course, everyone was aware of the problem long before 2017. On June 11, 2014, Publicis' John Dwyer was informed that the DEA believed "an oversupply of painkillers is fueling the black market for both prescription opioids and heroin," and furthermore that 668 individuals in the State of Massachusetts alone died of opioid overdoses in a single year (2012). In an internal Publicis email, Dwyer conceded, "in the opioid market there are so many other factors to consider than just 'how can we increase sales of our product?'"

481. Dwyer's expressed concern about "other factors to consider" when selling opioids is belied the by reality of Publicis actual work with Purdue, where "increasing sales of our product" was *literally* the goal Publicis were hired to pursue.[354] When the rubber meets the road, ROI is the only metric that matters.

482. Dwyer himself was in a unique position of knowledge. As a Publicis colleague told him in July 2016, "I doubt there's a marketer that knows the opioid marketplace like you do. You are speaking from a very secure place of knowledge in terms of RX targeting and who is driving RXs."

483. That knowledge was placed front and center in Publicis' pitch to the non-profit Partnership to End Addiction for work on the website drugfree.org. In the pitch, Dwyer and Razorfish Health Vice President Karl Tiedemann highlighted Publicis' deep knowledge of the opioid marketplace, and described its work for Purdue:

> We've been immersed in the evolving national opioid medication dialogue going on between pharma companies, the government and FDA, the media, and the public via **inside access as a trusted and informed consulting partner**… We've been ingrained in the evolution of these issues for 6 years as other companies have come

[354] *See* PPLPC018000873870 ([redacted])

and gone; monitoring the progress made with HCP's and patients. (emphasis added).

484. The detailed scope of Publicis' involvement in the opioid industry that Tiedemann and Dwyer set forth in their pitch to *a nonprofit combatting opioid addition* is remarkable. On March 1, 2016, Dwyer jotted down fifteen reasons why Publicis was "the indisputably most knowledgeable and most experienced agency to help with drugfree.org":

To: Karl Tiedemann[karl.tiedemann@razorfishhealth.com]; Scott Reese[scott.reese@razorfishhealth.com]
From: John Dwyer
Sent: Tue 3/1/2016 12:02:17 AM (UTC-05:00)
Subject: RFH experience for Drugfree.org

Some notes I jotted down summarizing our relevant experience in this area since 2010 that positions us as the indisputably most knowledgeable and most experienced agency to help with drugfree.org.

1. Worked with Purdue Pharma since Feb 2010
2. Not just on the promotion of their opioid medications OxyContin, Butrans, Targiniq and Hysingla ER
3. Worked on unbranded pain education program and website Partners Against Pain; rebranded, reinvented entire site twice including content and resources for HCPs, patients and caregivers
4. Worked on company branding and website PurduePharma.com in 2011 and again in 2015
5. Worked on Purdue's OxyContin REMS program materials for soft re-launch/re-brand of OxyContin for reformulation in Sept 2010
6. Agency selected to lead work creating branding and site content development for multi-pharma company-sponsored class wide ER and LA opioid REMS program in 2012
7. Developed strategy, messaging and brand campaign for OADP (opioids with abuse-deterrent properties) unbranded campaign used on teamagainstopioidabuse.com; site features content created for 7 stakeholder groups: Physicians; Patients/caregivers; Pharmacists; Payors; Parents and communities; Police and law enforcement; Pharma companies
8. Collaborated for the above with various departments outside of product Marketing: Public Affairs; Patient Advocacy; Promotional Med Ed; and programs Safeguard My Meds; Rx Safety Matters; In the Face of Pain; RxPatrol
9. Contributed to promotion and dissemination of all of the above via multi-channel promotion including websites, email campaigns, banner ads, convention materials, print ads, media buying, SEM (paid search), and SEO
10. Created the first oxycontin.com publicly accessible website including a Patient site with Patient content and materials
11. Participated in dozens of market research projects with hundreds of HCPs, payers, pharmacists and patients over 6 years
12. Attended pain and pain medicine conferences since 2010
13. Attended Advisory Boards with PCPs and multiple pain treating specialties
14. We've been immersed in the evolving national opioid medication dialogue going on between pharma companies, the government and FDA, the media, and the public via inside access as a trusted and informed consulting partner
15. We've been ingrained in the evolution of these issues for 6 years as other companies have come and gone; monitoring the progress made with HCPs and patients

John Dwyer
SVP, Group Account Director
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P 212.771.5428 M 917.797.9317

ii. Practice Fusion Knew

485. In April 2014, an internal email between Practice Fusion employees counseled that "indicating that Purdue influenced clinical decisions through sponsored money has legal

implications versus a marketing program where a banner can be displayed and influence a prescribing behavior."[355]

486. Practice Fusion knew which side of the line their conduct fell on. In a March 23, 2015, internal email, Practice Fusion discussed pitching CDS alerts to Purdue, and stated that Purdue "has communicated that the average dosage of OxyContin is declining," because prescribers are "hesitant about using high dosages to combat pain for a variety of reasons, mostly, political pressure." Because of this "pressure," Purdue might use Practice Fusion to boost prescriptions. "Purdue is toying with the idea of using Pain Assessment tools with the provider at every visit and before every RX."

487. In September 2015, a Practice Fusion employee advised a Practice Fusion colleague in an internal email, "I understand that the Purdue proposal has shifted to a commercial focus and that marketing folks were in the room instead of outcomes… there are several things incorrect with this presentation/proposal from pricing to products. Please do not share. Just be aware…"[356] That same month, another Practice Fusion employee wrote in a separate internal email describing a meeting with Purdue: "[W]e were talking to product managers, and they could care less about RWE [real world evidence]. For them, this was all about marketing."[357]

488. Practice Fusion knew that Purdue was only concerned about increasing prescriptions. On May 11, 2016, a Practice Fusion employee observed that in a meeting with Purdue to discuss the development of the CDS alert, he kept "hearing the client [Purdue] revert back to 'Rx lift' as the primary objective of the program, this came up in the kickoff meeting and

[355] Practice Fusion Information at Para. 27.
[356] Practice Fusion Information at Para. 58.
[357] Practice Fusion Information at Para. 60

again during last week's meeting." Repeatedly, Purdue made it clear to Practice Fusion what mattered.

489. Practice Fusion knew that even *Purdue* had legal concerns about the CDS alerts program. Purdue asked that Practice Fusion provide an update on the results of the CDS Program, including whether "the CDS alerts change prescribing behavior" with respect to EROS. The meeting between Practice Fusion and Purdue occurred on December 14, 2016. A Purdue attorney at the meeting expressed reservations about the CDS program and noted that the program had not received appropriate legal review within Purdue.[358]

490. A post-hoc legal review of the CDS alert program was conducted by Purdue with Practice Fusion's input in December 2016 and January 2017. Despite the legal review, none of the conduct that led to Purdue's subsequent guilty plea and Practice Fusion's deferred prosecution agreement was altered or paused. The conduct continued until 2019.

iii. ZS Knew

491. ZS was in a truly unique position, given its dominance of pharmaceutical sales and marketing consulting, practically all industry participants were its clients. While advising multiple industry participants regarding the sales of competing products (OxyContin and Opana, for instance) **at the same time**, ZS was in a position to know confidential information and trade secrets of these clients. Indeed, the contracts between ZS and its clients specify that ZS will have access to the clients' confidential and proprietary information. Given the nature of ZS' work, it cannot adequately perform its function for clients without that access.

492. ZS' clients were repeatedly subjected to enforcement actions for their work selling opioids both before and during the pendency of the ZS client relationship. For instance, in addition

[358] Practice Fusion Information at Para. 110.

to its 2007 guilty plea with the United States Department of Justice ("DOJ"), Purdue Pharma settled with the State of Kentucky in 2015 for $24 million.[359] The settlement concerned similar conduct as the 2007 guilty plea, including the sales and marketing of Purdue's opioids. ZS was involved in this work.

493. Two years later, on July 11, 2017, another ZS client settled charges that it failed to report suspicious orders of opioids and for various recordkeeping violations. In this case, Mallinckrodt's failure to comply with DEA regulations regarding the sales of opioids resulted in a $35 million payment to the DOJ.[360]

494. The settlement agreement related to conduct between 2008 and 2011, during which time ZS was advising Mallinckrodt.

495. Because of these client relationships, ZS was in a unique position to know how the entire industry's opioid sales and marketing tactics were playing out, both in terms of return on investment for their individual clients, as well as overall market trends such as the rise of the opioid crisis. Endo may not have known the specifics of competitor Purdue's marketing efforts for OxyContin, just as Purdue may not have known the specifics of Endo's Opana plan. But ZS knew both, as well as what Teva and Mallinckrodt were doing with their own branded opioid sales and marketing efforts *in real time*.

iv. Everyone Knew

496. The evidence of a direct link between increased opioids marketing and sales and increased opioid abuse was everywhere. A 2007 study found "a very strong correlation between

[359] *See* the December 22, 2015, settlement between the Commonwealth of Kentucky and Purdue Pharma Inc., *available* at https://ag.ky.gov/pdf_news/purduepharmaoxycontin.pdf.
[360] *See* https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[361] McKinsey evidently understands this. In a September 2016 online article, McKinsey asserts that "[t]here is no doubt that more consistent use of best practices – across geographic areas, institutions, and clinicians – would provide tremendous help in combating the crisis" and describes certain examples of such practices as "successful in reducing prescribing."[362]

497. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[363] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[364]

498. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[365]

499. Compounding the harm from deceptive marketing, Defendants worked with Purdue to continue and grow the opioid sales of prescribers that raised red flags of diversion, despite Purdue's legal obligations to report and halt supply. In doing so, it enabled an oversupply of opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids

[361] Theodore J Cicero *et al*., *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban*, *and Urban Locations in the United States*, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007), available at https://onlinelibrary.wiley.com/doi/10.1002/pds.1452.
[362]https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic
[363] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).
[364] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (Apr. 14, 2016).
[365] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al.* "Increases in drug and opioid overdose deaths – United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.

for both patients who could no longer access or afford prescription opioids and addicts struggling with relapse.

500. Most of the illicit use originates from prescribed opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

501. As McKinsey itself has recognized in citing a study reaching this conclusion, roughly 80% of heroin users previously used prescription opioids.[366] As many as one in four patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. And the link between prescription narcotic painkiller abuse and subsequent and/or simultaneous heroin abuse continues to grow.

502. In fact, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. A more recent, and even more deadly problem stemming from the prescription opioid epidemic involves fentanyl, a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Plaintiffs' communities.

503. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants, and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans.

504. No demographic is untouched by this epidemic. Nationally, one in five deaths among younger adults in 2016 involved opioids, according to one study. And deaths involving both prescription and illicit opioids have risen sharply, nearly doubling since 2009.

[366] https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic

505. Opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 183,000 people died in the United States from prescription-related overdoses.

506. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014 to 2016, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

507. In 2009, Dr. Van Zee identified the *precise tactics* that Defendants deployed for all of their opioid clients, including Purdue, as a source of OxyContin misuse and abuse, and suggested that regulation may be appropriate to curtail the use of the marketing tactics deployed by Defendants: "The use of prescriber profiling data to target high-opioid prescribers – coupled with very lucrative incentives for sales representatives – would seem to fuel increased prescribing by some physicians – perhaps the most liberal prescribers of opioids and, in some cases, the least discriminate."[367]

508. In time, additional evidence mounted supporting the conclusion that Defendants' sales and marketing tactics were demonstrably exacerbating the nationwide opioid crisis. One way of demonstrating the link between aggressive sales and marketing of opioids and worsened mortality outcomes arose out of a quirk of Purdue's own marketing tactics.

[367] Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99 AM. J. PUB. HEALTH 221, 221, 224 (Feb. 2009), *available at:* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf.

509. In 1996, when OxyContin was introduced, five states – California[368], Idaho, Illinois, New York and Texas – maintained "triplicate" programs that required prescribers of Schedule II controlled substances to fill out prescriptions in triplicate.[369] One of the triplicate copies would then be filed with the state agency in charge of maintaining a prescription database intended to monitor diversion and other potential issues relating to the over-dissemination of Schedule II narcotics. These triplicate programs were precursors to modern prescription drug monitoring programs that have been instituted in nearly every state in response to the opioid crisis.

510. Purdue recognized that the requirement to submit records of controlled substance prescriptions to a governmental database chilled prescribers' willingness to prescribe medications subject to the constraints of the triplicate programs. Because Purdue viewed these triplicate requirements as an overly burdensome hindrance on prescribing, the company chose to focus its marketing efforts in other states that did not impose these constraints.

511. This resource-allocation decision by Purdue to focus more marketing efforts in states with fewer regulations regarding the prescribing of controlled substances provided a way to test whether *marketing* of OxyContin, by itself, was a cause of not only increased overdose rates for OxyContin, but of *all* opioid-related overdoses, *including* those involving illicit opioids such as heroin and fentanyl.

512. The results were stark. In 2019, economists from the University of Pennsylvania, Notre Dame, and the RAND Corporation analyzed the disparate outcomes in overall opioid

[368] California was the first state to implement a triplicate program in response to concerns about the diversion of opium-based pharmaceuticals. The year was **1939**. *See* Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David Powell, *Origins of the Opioid Crisis and its Enduring Impacts*, NBER Working Paper No. 26500, November 2019, *available at*: https://www.nber.org/papers/w26500; *See also, supra.,* fn. 1.
[369] Patrick Radden Keefe, *Empire of Pain*, Pg. 407.

overdose mortality experienced in the triplicate states, where Purdue did not focus its marketing efforts, and non-triplicate states where Purdue did focus those efforts.[370]

513. The economists found that "OxyContin distribution was about 50% lower in 'triplicate states' in the years after the launch. While triplicate states had higher rates of overdose deaths prior to 1996, this relationship flipped shortly after the launch [of OxyContin] and triplicate states saw substantially slower growth in overdose deaths, continuing even twenty years after OxyContin's introduction. **Our results show that the introduction and marketing of OxyContin explain a substantial share of overdose deaths over the last two decades."**[371]

514. A 2017 *Journal of American Medical Association* study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[372] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

515. Separately, a recent *Journal of American Medical Association* study analyzed the Centers for Medicare and Medicaid Services' Open Payments database regarding pharmaceutical

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[370] Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David Powell, *Origins of the Opioid Crisis and its Enduring Impacts*, NBER Working Paper No. 26500, November 2019, *available at*: https://www.nber.org/papers/w26500

[371] *Id*. (emphasis added).

[372] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass'n 1785 (2017).

company marketing efforts towards doctors, as well as CDC data on prescription opioid overdose deaths and prescribing rates, in order to assess whether pharmaceutical marketing of opioids to physicians affected the rate of prescription opioid overdose deaths. Notably, the study analyzed these marketing practices beginning August 1, 2013, and ending December 31, 2015.[373]

516. Those dates are significant, as the study captures the same timeframe that McKinsey's Project Turbocharge, re-christened *E2E*, was implemented.

517. The study noted "physician prescribers are the most frequent source of prescription opioids for individuals who use opioids nonmedically."[374]

518. The study found that "increased county-level opioid marketing was associated with elevated overdose mortality 1 year later, an association mediated by opioid prescribing rates; per capita, **the number of marketing interactions with physicians demonstrated a stronger association with mortality** than the dollar value of marketing."[375]

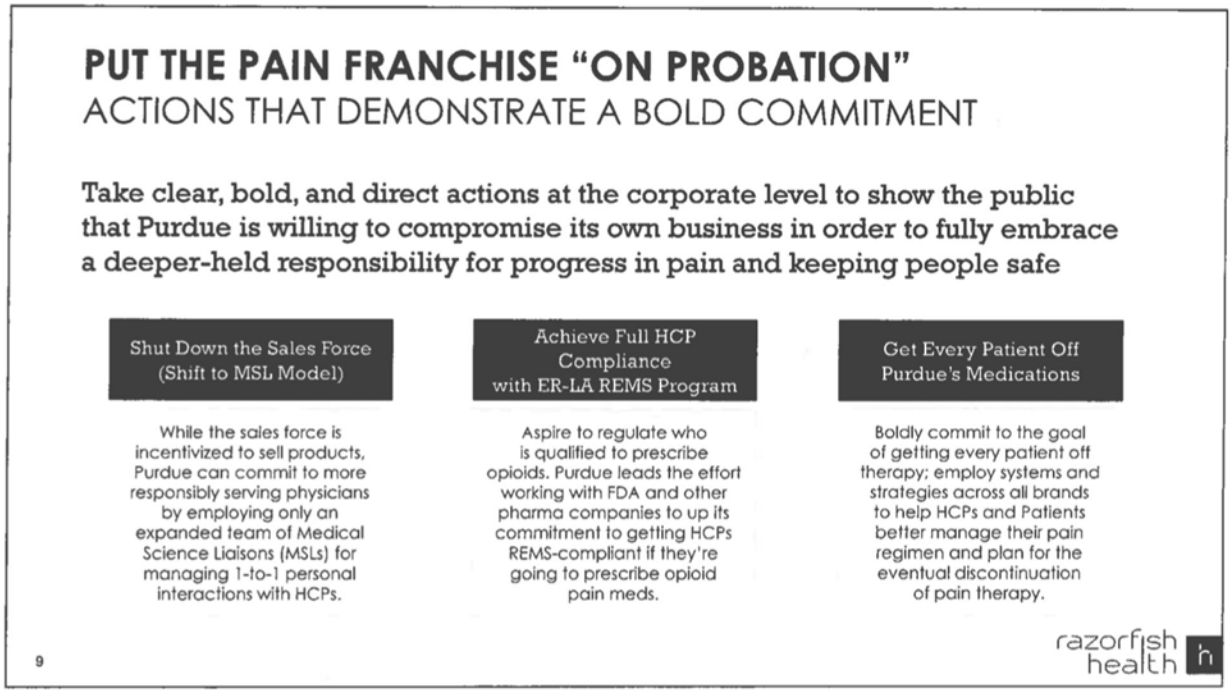
519. Referring to the types of sales and marketing tactics Publicis provided to its clients, and helped them implement, the authors concluded, "amid a worsening opioid crisis, our results suggest that industry marketing to physicians may run counter to current efforts to curb excessive opioid prescribing."[376]

520. The authors' proposed solution was plain simple, and echoed Dr. Van Zee's congressional testimony from 2002: "Pharmaceutical companies might also consider, as one

[373] Scott E. Hadland *et. al.*, *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related* Overdoses, JAMA Network, January 18, 2019, *available at:* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720914.
[374] *Id.*
[375] *Id.* (emphasis added)
[376] *Id*.

manufacturer recently did, **voluntarily ceasing marketing opioid products directly to physicians**."[377]

521. Incredibly, in an August 7, 2016, presentation to Purdue regarding their "Corporate Identity Transformation," Publicis offered, as one strategy *option* to be *considered* among others, voluntarily ceasing to market opioids in order to "fully embrace a deeper-held responsibility for progress in pain and keeping people safe." The pain franchise could be placed "on probation." It would be a "bold commitment:"



522. Defendants' role in the opioid industry was central. Given its overlapping engagements with multiple opioid manufacturers regarding the sales of competing products **at the same time**, Defendants were in a position to know the intricacies of the sales and marketing tactics of competing opioid sellers, including confidential information and trade secrets of these clients.

[377] *Id.*

And Publicis served as matchmaker to Defendant Practice Fusion, ushering it in to service opioid accounts like Purdue's that Publicis already controlled.

523. All the while, Defendants' clients were repeatedly subjected to enforcement actions for their work selling opioids both before and during the pendency of Defendants' client relationships. For instance, after its 2007 guilty plea with the United States Department of Justice ("DOJ"), Purdue Pharma settled with the State of Kentucky in 2015 for $24 million.[378] The settlement concerned similar conduct as the 2007 guilty plea, including the sales and marketing of Purdue's opioids. Defendants were all active participants in and contributors to this conduct.

524. Because of their extensive and long-term client relationships, Defendants were in a unique position to know how the entire industry's opioid sales and marketing tactics were playing out, both in terms of return on investment for their individual clients, as well as overall market trends such as the rise of the opioid crisis. Endo may not have known the specifics of competitor Purdue's marketing efforts for OxyContin, just as Purdue may not have known the specifics of Janssen's Nucynta plan. But McKinsey, Publicis, and ZS knew all three, as well as what Teva and others were doing with their own branded opioid sales and marketing efforts *in real time*.

525. As the modern opioid epidemic became apparent and the subject of nationwide attention, Defendants toiled diligently behind the scenes of several opioid manufacturers in the pursuit of one goal: maximizing volumes and profits from the sale of these addictive and deadly Schedule II controlled substances.

526. And so, through the affirmative acts undertaken by the Defendants, history repeats itself. This time, however, the devastation is on a scale previously unimaginable.

[378] *See* the December 22, 2015, settlement between the Commonwealth of Kentucky and Purdue Pharma Inc., *available* at https://ag.ky.gov/pdf_news/purduepharmaoxycontin.pdf.

V. TOLLING OF STATUTES OF LIMITATION

527. Defendants are equitably estopped from relying upon a statute of limitations defense. Alongside their clients, Defendants undertook active efforts to deceive Plaintiffs and to purposefully conceal its unlawful conduct and fraudulently assure the public, including Plaintiff, that opioids were non-addictive, effective, and safe for the treatment of long-term chronic pain and non-acute, non-cancer pain with the goal of increased sales, greater availability and access to opioids, and maximizing profits.

528. Defendants and their clients were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing of opioids. This deceptive marketing—which included the above falsehoods that opioids were safer, less subject to abuse, and less addictive than other pain medications—was a substantial factor in the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

529. Defendants deliberately advised their clients on marketing strategies and tactics to bolster their opioid products as non-addictive, safe, and efficacious without reliable scientific evidence to support same, and implemented the same. Defendants' services were given confidentially, and both Defendants and their clients concealed the content of those services from the public. In doing so, Defendants concealed their role in shaping, editing, and providing the content of the false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers, and the public at large, including Plaintiff.

530. Defendants also concealed from Plaintiff the existence of the Plaintiff's claims by hiding their and their client's lack of cooperation with law enforcement. For example, in May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction and entered into a Corporate Integrity Agreement explained above. Purdue was ordered to pay

$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

531. Nevertheless, even after the guilty pleas, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. Purdue also assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during that period. Defendants participated extensively in these actions and provided Purdue with strategies and assistance to maximize sales as described in this Complaint. Defendants knew that the actions they took with Purdue were unlawful, and yet deliberately proceeded in order to increase Purdue's sales and profits, and in turn to serve Defendants' financial interests.

532. Defendants affirmatively sought to convince the public that its clients' legal duties to report suspicious sales of opioids had been satisfied through public assurances that they were working to curb the opioid epidemic. For example, after the 2007 Purdue guilty plea described above, Defendants provided services to protect the company's public image and sales, aiding in the concealment of the addictive nature and dangers associated with opioid use and denying blame for the epidemic, attributing it instead solely to abuse and inappropriate prescribing. At the

guidance and advice of Defendants, Purdue and others publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways, insisting they were good corporate citizens. Instead, Defendants assisted Purdue, for example, with marketing campaigns and messaging that continued business as usual, indiscriminately targeting high prescribers and promoting opioids as safe but avoiding the pitfalls of the Corporate Integrity Agreement. These repeated misrepresentations misled regulators, prescribers, and the public, including the Plaintiffs, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put the Plaintiff on notice of potential claims.

533. Plaintiff did not discover the nature, scope, and magnitude of Defendants' misconduct, and its full impact on Plaintiff, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

534. Prior to the applicable limitations period, Plaintiff did not suspect, and had no reason to suspect, that Defendants' conduct caused their injuries, including the consumption of Plaintiff's resources as the opioid epidemic remains unabated.

535. Defendants intended that its actions and omissions made with its clients would be relied upon, including by the Plaintiff. The Plaintiff did not know and did not have the means to know the truth due to Defendants' and their clients' actions and omissions.

536. The Plaintiff reasonably relied on the affirmative statements developed by Defendants and made by their clients regarding their purported compliance with their obligations under the law and consent orders, which were false and only intended to save the clients' public image.

537. Defendants' fraudulent concealment has tolled the running of any statute of limitations. Through their and their clients' affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff the risks associated with opioids that led to the opioid crisis. The wrongdoing, misrepresentations, and omissions by Defendants have not ceased because the public nuisance remains unabated.

VI. HARM TO SCHOOL DISTRICTS AND STATE CLASSES

538. Defendants' intentional and/or unlawful conduct described herein resulted in direct and foreseeable, past and continuing, economic damages which Plaintiffs and the State Classes have incurred and continue to incur, including: 1) costs associated with special education including, but not limited to, special programs for children with opioid-related learning disabilities, or for children in need of psychological counseling or other supports due to opioid-related family crisis; 2) costs associated with providing care and support for children whose family members suffer from opioid-related disability or incapacitation and/or opioid use disorder; 3) costs associated with increased school security in all facilities of the school board district; 4) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; 5) costs regarding disability payments; 6) loss of tax revenue; and 7) treble damages, and for which Plaintiff seeks relief as to all claims and counts alleged herein. Plaintiff also seeks the means to abate the epidemic, including but not limited to economic damages from Defendants as reimbursement for the costs associated with past, present, and future efforts to address, pay for, and/or eliminate the aforementioned hazards to public health and safety.

539. Plaintiffs, and similarly situated school districts in their states, have had to increase resources or divert resources away from other essential functions because of Defendants' schemes to increase opioid sales. The costs to schools have included increased disability evaluations,

increased numbers of students qualifying for educational disability, increased classroom therapies and services, increased administrative expenses, and resources increasingly diverted from classroom instruction to address behavioral disruptions caused by students whose ability to self-regulate has been compromised by prenatal opioid exposure or their families' addiction to opioids.

540. A significantly higher proportion of children with a history of NOWS are diagnosed with educational disabilities, including developmental delay or speech or language impairment. They are more likely to have severe intellectual disabilities, autism spectrum disorders, or Attention Deficit Disorder. They are also more likely to fail to meet grade level norms. These differences, individually and in combination make children with a history of NOWS significantly and disproportionately more likely to qualify for and receive mandated special education services.[379]

541. In all states where Plaintiffs are located, Defendants conspired with and aided and abetted numerous opioid manufacturers to flood those states with prescription opioids, causing an increase in babies born with NOWS in those states and an increase in enrollment by students with NOWS histories in Plaintiff school districts. The states in which the school districts bringing this Complaint are located have all suffered harm.

[379] Chasnoff, IJ, Seiger ML (2023) *Prenatal Opioid Exposure and Special Education Needs: A Sibling Study*, Adv Pediatr Res. 10:069; *see also* Mary-Margaret A. Fill et al., *Educational Disabilities Among Children Born With Neonatal Abstinence Syndrome*, 142 Pediatrics e20180562 (2018); Oei JL, Mulhuish E, Uebel H, et al., *Neonatal Abstinence Syndrome and High School Performance*, 139 Pediatrics 2 (2017); Sirnes, Eivind, et al., "Brain morphology in school-aged children with prenatal opioid exposure: a structural MRI study," *Early Human Development* 106 (2017), 33-39.

In addition, eighty percent of children with ADHD receive school-based services via federally mandated Individual Education Plans ("IEPs") or services pursuant to Section 504 of the Rehabilitation Act. *See* Danielson, Melissa L. et al., "A national description of treatment among United States children and adolescents with attention-deficit/hyperactivity disorder," *The Journal of Pediatrics* 192 (2018): 240-46.

VII. CLASS ALLEGATIONS

542. Plaintiffs bring this case on behalf of themselves and as statewide class actions under Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) and, alternatively, 23(c)(4) on behalf of all independent public school districts in their respective states ("the State Classes"). All class members bear the steadily rising costs of providing special education and related supports and services and diversion of resources to their states to provide for (1) children exposed to opioids *in utero,* which makes those children about twice as likely to exhibit learning and developmental disabilities than children who were not exposed,[380] and (2) children presenting emotional and behavioral challenges in schools because of their family members' use of opioids.

543. Plaintiffs and the State Classes will continue to incur significant costs in the years to come as the current and future cohorts of adversely impacted children come of school age and move from lower school to high school with special needs all along the way.

544. Plaintiffs' State Classes are defined as follows:

a. Illinois: All independent public school districts in the State of Illinois

b. Ohio: All independent public school districts in the State of Ohio

c. Maryland: All independent public school districts in the State of Maryland

d. New Mexico: All independent public school districts in the State of New Mexico

e. California: All independent public school districts in the State of California

f. Maine: All independent public school districts in the State of Maine

g. New York: All independent public school districts in the State of New York

[380] Paul Morgan and Yangyang Wang, *The Opioid Epidemic, Neonatal Abstinence Syndrome, and Estimated Costs for Special Education Services*, 25 American Journal of Managed Care 13 (2019).

545. Plaintiffs reserve the right to amend or modify the class definitions with greater specificity or further division into subclasses or limitation to particular issues.

546. Numerosity. The potential members of the State Classes as defined as so numerous that joinder of all members is unfeasible and not practicable. There are 852 school districts in Illinois, 611 in Ohio, 24 in Maryland, 111 in New Mexico, 937 in California, 263 in Maine, 73 in Florida, and 731 in New York.

547. Commonality and Predominance. There are questions of law and fact common to the State Classes, which predominate over any questions affecting only individual State Class members. These common questions of law and fact include, without limitation:

a. Defendants' conduct in creating, recommending, and implementing marketing, promotion, distribution, and sales strategies for opioids after Purdue's first guilty plea in 2007;

b. Whether Defendants disregarded the risks associated with its strategies for maximizing sales and return on investment for opioid products;

c. Whether Defendants' conduct in creating, recommending, and implementing nationwide opioid sales strategies for numerous opioid manufacturers caused or contributed to an increase in opioid addiction and abuse and the effect alleged;

d. Whether Defendants' conduct with respect to their opioid clients was negligent, grossly negligent, reckless, or intentional;

e. Whether Defendants' conduct caused or contributed to a public nuisance;

f. Whether Defendants' conduct resulted in false misrepresentations to prescribers, including those within each State Class's state, regarding opioids;

g. Whether Defendants aided and abetted and/or conspired with Purdue, Rhodes, the Sackler family, and other opioid manufacturers in creating, recommending, and implementing their opioid sales and marketing strategies;

h. Whether Defendants' conduct caused an increase in the number of children born with *in utero* opioid exposure;

i. Whether children affected by opioid usage *in utero* require special education services and other supports in public schools; and

j. Whether opioid addiction or use disorder in the family home increases the risk that a student will present emotional and behavioral difficulties in school.

548. Typicality. The claims of the named Plaintiffs are typical of the claims of each of their State Classes. Plaintiffs and the State Classes sustained damages as aforesaid arising out of and caused by Defendants' unlawful conduct as alleged herein.

549. Adequacy of Representation. Plaintiffs will fairly and adequately represent and protect the interests of the members of their State Class. Counsel representing Plaintiffs are competent and experienced in litigation class actions.

550. Superiority of Class Action. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all the members of the State Classes is impracticable. Furthermore, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and potentially conflicting adjudication of the claims asserted. A class action would provide a superior vehicle for resolving the issues for all similarly affected and situated. There will be no difficulty in the management of this action as a class action.

VIII. CAUSES OF ACTION

COUNT I:
Racketeer Influenced and Corrupt Organizations Act (RICO)

1. Plaintiffs re-allege all of the foregoing allegations and incorporate them herein by reference.

2. This claim is brought by Plaintiffs against Defendants for actual damages, treble damages, and available injunctive and/or equitable relief under 18. U.S.C. § 1964, for violations of 18 U.S.C. § 1961, *et seq.*, specifically, 18 U.S.C. § 1962(c) and (d).

3. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . ." 18 U.S.C. § 1962(c).

4. At all relevant times, each Defendant is and has been a "person" under 18 U.S.C. § 1961(3) because each is capable of holding, and does hold, "a legal or beneficial interest in property."

5. Plaintiffs are each a "person," as the term is defined in 18 U.S.C. § 1961(3), and have standing to sue under 18 U.S.C. § 1964(c) as they were and are injured in their business and/or property "by reason of" the RICO Act violations described herein.

6. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. See 18 U.S.C. § 1962(d).

7. Defendants conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

Description of the Enterprise

8. Section 1961(4) defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

9. Under 18 U.S.C. § 1961(4), a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

10. Opioid manufacturers, including Purdue, Johnson & Johnson, Janssen, Cephalon, Endo, and Mallinckrodt (collectively the "Opioid Manufacturers"), together with Defendants and McKinsey ("the Opioid Consultants"), participated in the marketing and sale of opioids as described in this Complaint, (collectively, the "Opioid Marketing Enterprise Members" or the "Enterprise Members") engaged in a scheme to unlawfully increase sales of opioids— both by growing their share of the prescription painkiller market *and* by growing the market as a whole— through repeated and systematic misrepresentations, concealments, and omissions of material fact about the safety and efficacy of opioids for treating long-term chronic pain, together with other deceptive and fraudulent acts and practices, as described in the Factual Allegations section of this Complaint and in the Master Consolidated Complaint filed by Plaintiffs in MDL 2996 on December 6, 2021, *cf.* Dkt. 297 (School District Master Complaint).

11. In order to unlawfully increase the demand for opioids and thereby increase their own profits despite their knowledge of the harmful effects that would follow, the Opioid Marketing Enterprise Members formed an association-in-fact enterprise (the "Opioid Marketing Enterprise" or the "Enterprise"). The Opioids Manufacturers worked together to accomplish their aims, with McKinsey and Defendants serving as go-betweens that held all of the companies together and

helped design and coordinate the deceptive marketing and sales strategies. Through McKinsey and Defendants and their own personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose: lying to prescribers and Plaintiffs in order to increase sales of addictive and dangerous drugs and line the enterprise members' pockets. The Opioid Marketing Enterprise Members' substantial financial contributions to the Opioid Marketing Enterprise and the advancement of opioids-friendly messaging fueled the U.S. opioid epidemic.

12. In the alternative, the association-in-fact Opioid Marketing Enterprise existed just between McKinsey, Defendants, and Purdue, who worked together to unlawfully increase sales of *all* opioids—not just Purdue's own products—through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain. McKinsey and Defendants knew Purdue was marketing its opioids illegally and fueling an opioid epidemic, but using the knowledge gained from Defendants' and McKinsey's work with other opioid manufacturers, Defendants and McKinsey joined forces with Purdue to turbocharge the opioids market in order to profit from this crisis.

13. The Controlled Substances Act (the "CSA") and its implementing regulations require that "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance," including opioids, become a "registrant." *See* 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.11(a). These registrants, including opioid manufacturer and distributors, must maintain a system to identify and report suspicious orders, including orders of unusual size or frequency, or orders deviating from a normal pattern, and maintain effective controls against diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

14. Despite these duties, Defendants, McKinsey and the other Enterprise Members engaged in a scheme with the overarching purpose of materially expanding prescription opioid use by altering the medical community's opioid prescribing practices through repeated fraudulent statements and misrepresentations. The Opioid Marketing Enterprise's scheme was sophisticated, well-developed, and fraudulent and was designed to increase the prescription rate for opioid medications the Enterprise Members knew where dangerous and highly addictive. At all relevant times, Defendants and McKinsey were aware of the conduct of the Enterprise, were knowing and willing participants in that conduct, and reaped profits from that conduct in the form of payments from other Enterprise Members as a reward for work done to increase sales and distribution of prescription opioids.

The Common Purpose and Scheme of the Opioid Marketing Enterprise.

15. The Opioid Marketing Enterprise Members, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and Plaintiffs and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. These misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition, which the Opioid Marketing Enterprise Members named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

16. The scheme devised, implemented, and conducted by the Opioid Marketing Enterprise Members was a common course of conduct designed to ensure that the Opioid Marketing Enterprise Members unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Opioid Manufacturers' drugs. The Opioid Marketing Enterprise Members acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme.

17. There was regular communication between the Opioid Marketing Enterprise Members in which information was shared, misrepresentations were coordinated, and payments were exchanged. The Opioid Marketing Enterprise Members functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

18. As public scrutiny and media coverage focused on how opioids ravaged communities throughout the United States, Defendants and McKinsey did not challenge Purdue or other manufacturers' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence. Instead, despite its knowledge of the ongoing fraud and the danger it posed, Defendants and McKinsey continued to participate in the Opioid Marketing Enterprise for financial gain.

19. The impact of the Opioid Marketing Enterprise's scheme is still in place—i.e., the opioids continue to be prescribed and used for chronic pain throughout the United States, and the epidemic continues to injure Plaintiffs and consume the resources of Plaintiffs.

20. The evidence shows that the Opioid Marketing Enterprise Members, including Defendants and McKinsey, were each willing participants in the Opioid Marketing Enterprise, had

a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

The Conduct of the Opioid Marketing Enterprise Violated Civil RICO.

21. From at least 2004 to the present, each of the Opioid Marketing Enterprise Members played some part in directing the affairs of the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

22. Creating and providing a body of deceptive, misleading, and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

23. Creating and providing a body of deceptive, misleading, and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

24. Creating and providing a body of deceptive, misleading, and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

25. Devising and implementing marketing schemes that included targeting and misleading physicians, unlawfully incentivizing sales representatives to maximize prescriptions and dosages, and evading regulatory constraints; and

26. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications.

27. The scheme devised and implemented by the Opioid Marketing Enterprise Members amounted to a common course of conduct intended to enrich themselves by increasing sales of prescription opioids by convincing doctors to prescribe and patients to use opioids, including for long-term chronic pain, despite the Opioid Marketing Enterprise Members' knowledge of the addictions and deaths that would occur as a result. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

The Opioid Marketing Enterprise Members Conducted or Participated, Directly or Indirectly, in the Conduct of the Enterprise's Affairs.

28. "[T]o conduct or participate, directly or indirectly, in the conduct" of an enterprise, "one must participate in the operation or management of the enterprise itself." *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993).

29. As described herein, the Opioid Marketing Enterprise Members participated in the conduct of the Enterprise through a pattern of racketeering activity, and Defendants and McKinsey were the masterminds of marketing schemes deployed by the Enterprise members to defraud prescribers and Plaintiffs by using the mail and wires in furtherance of plans that were designed with specific intent to defraud.

30. The Opioid Marketing Enterprise Members conducted an association-in-fact enterprise and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, i.e., to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term, chronic pain. Through the racketeering activities of

the Opioid Marketing Enterprise, the Opioid Marketing Enterprise Members sought to further the common purpose of the Enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use. In so doing, each of the Opioid Marketing Enterprise Members knowingly conducted and participated in the conduct of the Enterprise by engaging in mail and wire fraud, in violation of 18 U.S.C. §§ 1962(c) and (d).

31. The Opioid Marketing Enterprise is an association-in-fact enterprise that consists of the Opioid Marketing Enterprise Members.

32. Each of the Opioid Marketing Enterprise Members conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the Enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order to increase the market for prescription opioids by changing prescriber habits and public perceptions.

33. Specifically, the Opioid Marketing Enterprise Members each worked together to coordinate the Enterprise's goals and conceal their role, and the Enterprise's existence, from prescribers and Plaintiffs by, among other things, (i) funding, creating, editing, and distributing publications that supported and advanced their false messages; (ii) funding key opinion leaders ("KOLs") to further promote their false messages; and (iii) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians.

34. Further, each of the Opioid Marketing Enterprise Members had systematic links to, and personal relationships with, each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed the Opioid

Marketing Enterprise Members the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the Opioid Marketing Enterprise Members coordinated their efforts through the same KOLs and front groups, based on their agreement and understanding that the front groups and KOLs were industry friendly and would work together with the Opioid Marketing Enterprise Members to advance the common purpose of the Opioid Marketing Enterprise; and each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

35. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each Opioid Manufacturer and its members; (b) was separate and distinct from the pattern of racketeering in which the Opioid Marketing Enterprise Members engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Opioid Marketing Enterprise Members; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise; and (e) had sufficient longevity for the Enterprise to pursue its purpose and functioned as a continuing unit.

36. The Opioid Marketing Enterprise Members conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids and expand the market for opioids.

37. The Opioid Marketing Enterprise Members each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Opioid Marketing Enterprise Members committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Opioid Marketing Enterprise Members' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail, and interstate wire facilities. The Opioid Marketing Enterprise Members participated in the scheme to defraud by using mail, telephones, and the internet to transmit communications and payments in interstate or foreign commerce.

The Conduct was More than a Typical Business Relationship.

38. There were strong relationships among those associated with the Opioid Enterprise and sufficient longevity among Enterprise associates to pursue the Enterprise's common purpose. The common purpose was to increase opioid revenues unlawfully by misrepresenting and lying about opioids in order to changing prescriber habits and the perception regarding the safety and efficacy of opioids for chronic pain and long-term use. The Enterprise's deceit was, in part, in its failure to disclose that increasing strength and dosing actually increased the risk of addiction and overdose and that patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief.

39. On March 1, 2004, McKinsey entered into a "Master Consulting Agreement" with Purdue for "services that would be defined from time to time."[381] The Master Consulting Agreement was signed by then-McKinsey director Rob Rosiello.[382]

40. From 2004 through 2008, McKinsey advised Purdue on research and development, business development, and product licensing related to Purdue's opioid products.[383] Consistent with its business model, McKinsey leveraged these projects into growth of its "Broader Strategy work" also underway with Purdue.[384] Specifically, in October 2008, Purdue retained McKinsey for broad strategy work after two board members "blessed" Purdue executive Craig Landau with doing "whatever he thinks is necessary to 'save the business'" after the 2007 criminal plea and introduction of generic competition to the older OxyContin.[385] Purdue relied heavily on McKinsey to help Purdue publicly portray itself as a good corporate citizen who could now be trusted and was even working on an "abuse-deterrent" or "ADF" form of OxyContin. Defendant Publicis worked intimately with McKinsey is designing and disseminating these messages to their intended audience.

41. Over their many years of working together, McKinsey and Richard Sackler developed a close relationship. Indeed, one McKinsey partner, Maria Gordian, describes herself as a counselor to Richard Sackler in an "Ey 2009 Impact Summary."[386]

42. For Publicis' part, they owned their client. Publicis' Karl Tiedemann noted in an email the "amazing relationship" developing between Purdue and Publicis, and quoted a Purdue

[381] MCK-MDL2996-0085849; PPLPC012000069192
[382] MCK-MDL2996-0085849, at 0085880.
[383] PPLPC013000116218; PPLP004401340
[384] MCK-MAAG-0117875
[385] MCK-MAAG-0117875
[386] MCK-MAAG-0118669

employee as stating that the Hysinglia account was "the final piece and **we now own Purdue."** (emphasis added).

43. The Opioid Marketing Enterprise was more than a typical business relationship. Rather, the members of the Enterprise knew that opioids were addictive and causing serious harm to people and communities but chose to work together to lie to prescribers and Plaintiffs about these drugs in order to increase their bottom lines. Defendants and McKinsey worked closely with the Opioid Manufacturers to achieve these aims. Defendants and McKinsey, as advisors to multiple Opioid Manufacturers, also had access to information about multiple players and was able to coordinate the fraud occurring across the Enterprise. As discussed below, McKinsey was particularly embedded in Purdue's organizational structure and the relationship's longevity was sufficient to pursue the Enterprise's purposes. During the 2009-2014 period in particular, Purdue relied extensively on McKinsey to develop its sales and marketing strategy for OxyContin. Publicis worked with McKinsey and Purdue to craft and disseminate these strategies by using targeting and salesforce optimization methods designed by ZS and distribution channels offered by Practice Fusion.

44. The intent to defraud is evident in the Defendants and McKinsey's attempts to strengthen their relationships with Purdue and assist Purdue in selling opioids after Purdue's 2007 criminal guilty plea. As part of the guilty plea, Purdue admitted that its "supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medication."[387] But rather than be deterred by this, Defendants and McKinsey dove in. In a March 2009 self-assessment, Ms. Gordian described McKinsey's progress in having

[387] Information at pp. 5-6, *United States v. Purdue Frederick Co.*, No. 07-cr-29-JPJ (W.D. Va. May 10, 2007), Doc. 5.

"continue[d] to expand the depth and breadth of [its] relationships with Purdue" and plans to "deepen[]" McKinsey's "relationship with the Sackler family," including by "serving them on key business development issues" and "expanding" McKinsey's relationship with members of Purdue's senior management team.[388] Meanwhile, internal Rosetta communications refer to Publicis "owning" Purdue given the extent of their relationship with the client, to wit, "we now own them."

45. By August 2009, Richard Sackler had convened a meeting of Purdue board members and staff to discuss efforts to "reverse the decline in the OxyContin tablets market."[389] During the 2009-2014 period in particular, Purdue relied extensively on Defendants and McKinsey to develop and implement sales and marketing strategy for OxyContin. Defendants and McKinsey worked closely with Purdue on both the creation and implementation of OxyContin sales strategy. McKinsey's work for Purdue included consulting, review of product acquisition, evaluation of research and development, advising Purdue on the design of clinical studies, risk management, and product marketing.[390]

46. On May 28, 2013, McKinsey entered into a "Statement of Services to the Master Consulting Agreement" (the "2013 Agreement") with Purdue to "conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities."[391] The 2013 Agreement stated, "We have a long history of partnership with Purdue, and we would make best efforts to leverage our understanding of your business—both in terms of content and culture." The

[388] MCK-MAAG-0118669
[389] PPLPC061000045395
[390] PPLPC029000547371
[391] Excerpt from U.S. Department of Justice Plea Agreement with Purdue Pharma L.P. October 20, 2020. 18, ¶88. https://www.justice.gov/opa/press-release/file/1329576/download.

2013 Agreement was signed by then-principal Arnab Ghatak who would "lead the team with senior leadership from Rob Rosiello and Martin Elling."

47. McKinsey continued to work with Purdue on strategies to boost the sales of its opioid products, in particular OxyContin, through 2017, when Purdue, which soon would be facing hundreds of lawsuits arising out if its role in the opioid epidemic, reduced its investment in sales.[392] Throughout that time period, Defendants worked alongside Purdue and McKinsey to design, implement and disseminate these strategies.

48. Thereby, even after the 2007 guilty plea, Purdue, with Defendants and McKinsey's ongoing aid and assistance, saw growing profits from opioid sales. In 2015 alone, Purdue obtained $3 billion in annual opioid sales—a four-fold increase from its 2006 sales of $800 million.

49. Defendants and McKinsey's relationship with Purdue went far beyond a typical business relationship. Defendants and McKinsey worked closely with Purdue on both the creation and implementation of OxyContin sales strategy, a strategy Defendants and McKinsey knew had been based on misleading and defrauding doctors and patients alike about a dangerous and highly addictive drug. McKinsey and Defendants interacted with Purdue at all levels of the corporate hierarchy – from fields sales representative all the way up to Purdue's Sackler-controlled board of directors.

50. Further, Defendants and McKinsey had access to detailed prescribing information enabling them to determine if there were suspicious or problematic prescribing patterns. Rather than using this information to help their clients prevent diversion of controlled substances, Defendants and McKinsey and the Opioid Marketing Enterprise used this information in furtherance of their scheme to defraud prescribers and Plaintiffs, target and increase sales to

[392] PPLPC018001462324 [redacted]

prescribers who were overprescribing, and continue to fuel opioid addiction and the resulting epidemic.

The Fraudulent Schemes

51. As detailed above, the operation of the Opioid Marketing Enterprise, included several schemes to defraud that helped to further the goals its members—i.e., to expand the market and increase profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and to increase profits for the Enterprise Members via expanding the market for opioids.

Fraudulent Marketing Scheme: Deceptive Messaging Regarding Opioid Use

52. As described throughout, Defendants and McKinsey sought to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term, chronic pain by changing prescriber habits and public perception regarding the safety and efficacy of opioids. Defendants' and McKinsey's fraud specifically targeted prescribers and set out to convince them that they should prescribe more and more opioids, overcoming what could otherwise be a check on opioid manufacturers ability to increase sales of addictive products.

53. Despite Defendants and McKinsey knowing that reformulated OxyContin could still be abused, having advised Purdue on the design of tests of reformulated OxyContin as part of Purdue's FDA submission,[393] in furtherance of the scheme to defraud, Defendants and McKinsey spread messages that prescribing opioids could provide "freedom" and "peace of mind" for its users and that physicians could "tailor the dose."

54. After Purdue's 2007 criminal plea for illegally marketing OxyContin, Defendants and McKinsey created strategies to repair Purdue's reputation and boost OxyContin sales. In 2008,

[393] McK-MAAG-0118669

Purdue submitted a New Drug Application for a reformulation of OxyContin, ostensibly to make it more difficult to abuse by extracting the active ingredient from it or otherwise defeating the time-release mechanism in OxyContin tablets—i.e., another product Purdue would later deceptively promote as safer than and less prone to abuse than it was.

55. In June 2009, McKinsey helped Purdue prepare for an FDA advisory committee meeting. Among other recommendations, McKinsey advised that "we will need to be ready with the right messages."[394] It also cautioned that that there was a perception of Purdue as "disingenuous, trying to expand the OxyContin market by reformulating" and suggested that Purdue "explicitly quash[]" such concerns with assurances that this was not its intent.[395]

56. McKinsey prepared for Purdue an "FDA Advisory Committee on Reformulated OxyContin: Question & Answer Book" in September 2009, with questions including "Why should we trust you?" In response, McKinsey recommended Purdue say "We acknowledge mistakes made in the past"; "We have x, y and z measures in place that did not exist before"; and "[a]t all levels, Purdue's focus is on maintaining the highest ethical standards and meeting the needs of patients."[396] To the question of "Who at Purdue takes personal responsibility for all these deaths?[,]" McKinsey recommended Purdue say, "We all feel responsible[.]"

57. As described above, Defendant Publicis also engaged in work with the FDA, and through that work was able to disseminate messages consistent with Purdue's strategy to increase overall opioid prescribing.

58. Defendants and McKinsey and the other Opioid Marketing Enterprise Members knew the changes Purdue made would not make opioids non-addictive or prevent them from being

[394] PDD8901645845
[395] *Id.*
[396] MCK-MAAK-0152135

used to create and further substance abuse problems. For example, in 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." Similarly, in approving reformulated OxyContin, the FDA cautioned that the reformulation "is not completely tamper resistant and those intent on abusing this new formulation will likely find a means to do so. In addition, the product can still be misused or abused and result in overdose by simply administering or ingesting larger than recommended oral doses."[397]

59. Despite this knowledge, the Opioid Marketing Enterprise pursued messaging and a strategy that was deceptive and was designed to deceive doctors in particular. Even after Purdue pleaded guilty to offenses related to its marketing and distribution of addictive opioids, Defendants and McKinsey advised Purdue to market OxyContin to encourage more prescriptions (that it knew would lead to abuse and overdose events) into higher dose prescriptions by a smaller number of loyalist prescribers.

60. Rather than the deception of doctors being an unforeseen consequence, Defendants and McKinsey intentionally set out to target doctors as a cog in the Enterprise's scheme to defraud. Indeed, deceiving doctors was part of the marketing scheme, and doctors were utilized in furtherance of the marketing scheme. Medical providers were not a break in the causal chain of harm to Plaintiffs but were targeted players in the scheme to defraud and key links in the casual chain.

61. The marketing scheme involved using data to target high prescribers and training marketers to make misleading statements with the goal to increase high dose prescriptions which Defendants and McKinsey and Opioid Marketing Enterprise Members knew were more likely to

[397] FDA Summary Review, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000SumR.pdf

be abused. Enterprise Members knew that overdoses were expected and that such overdoses would lead to need for increased services.

62. Purdue's 2020 guilty plea acknowledged its role in using aggressive marketing to convince doctors to prescribe opioids unnecessarily, fueling the drug addiction crisis. Defendants and McKinsey were the masterminds of marketing scheme following Purdue's 2007 guilty plea. Defendants and McKinsey developed and helped implement these strategies.

63. In an October 26, 2009 presentation, "OxyContin – driving growth through stronger brand loyalty," McKinsey proposed tactics to turnaround declining sales, "[e]nhance loyalty to OxyContin among loyalist prescribers," "convert[ing] 'fence sitters' into more loyal OxyContin prescribers,"[398] and "protect OxyContin's market share[.]"[399] In other words, McKinsey proposed increasing sales by pushing both willing and reluctant physicians to prescribe more OxyContin. Defendants worked assiduously alongside McKinsey to accomplish these goals.

64. Defendants and McKinsey recommended segmenting prescribers and tailoring messages and tactics to different segments. For prescribers dubbed "Early Adopting Experts" and "Proactive Teachers," defined by a willingness to use extended release opioids, including in patients who were not already using opioids, McKinsey urged emphasizing that its 7 tablet strengths provide flexibility to "tailor the dose" to customer needs.[400] Upon information and belief, this message aimed to encourage prescribers to initiate and maintain patients on OxyContin long-term by reminding them they could increase the dose as patients became tolerant with long-term use (rather than discontinue use when the drug lost its effectiveness).

[398] MCK-MDL2996-0126522
[399] *Id.* at 2
[400] *Id.* at 12.

65. Purdue adopted McKinsey's prescriber segmentation proposal.[401] Further, many of the messages McKinsey urged appeared in OxyContin promotional materials from 2009 to 2012, including the "Conversion and Titration Guide," which included similar claims about "tailoring the dose."[402] Defendants Publicis and ZS were integral to these prescriber segmentation efforts, and Publicis worked for years to continually refine titration messaging for Purdue to ensure each prescription was as profitable as possible.

66. As detailed throughout, Defendants and McKinsey and Opioid Marketing Enterprise Members were aware of the catastrophic injury inflected on the public by selling harmful, addictive opioid products. Yet when promoting opioids and engaging in doctor detailing, the Enterprise Members intentionally hid the potential for abuse and addiction by marketing OxyContin's 12-hour dosing as meaning that users only need to take OxyContin twice a day, thus requiring fewer pills.

67. It was foreseeable that this marketing strategy would lead to greater addiction because OxyContin wore off after 8 to 10 hours in many patients. Prescribing 12-hour dosing led to "end of dose failure," which led to a vicious cycle that became "the perfect recipe for addiction."[403] As a result, what Defendants and McKinsey marketed as "convenient" led to what was described as "a [d]escription of Hell."[404]

68. The marketing scheme worked. Nationwide, based on an analysis by the Los Angeles Times, more than 52% of patients taking OxyContin longer than three months are on

[401] PPLPC023000251226 ( ); see also PPLPC012000243668 ( ); PPLPC012000245087 ( ); PPLPC012000246009 (PPLPC021000265092 ( )

[402] PKY183123435

[403] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/.

[404] *Id.*

doses greater than 60 milligrams per day—which converts to the 90 morphine equivalent dose that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[405]

69. A key element of the marketing scheme that fueled the deadly epidemic of opioid abuse was doctor detailing using detailed prescriber data.

Data Scheme: Use of Prescriber Data for Intentional Targeting of High Opioid Prescribers-Not Diversion Prevention

70. Defendants and McKinsey were advisors to DEA registrants and Opioid Marketing Enterprise Members, who had a legal duty to guard against diversion and report suspicious orders of controlled substances. Rather than assisting in reporting suspicious orders, Defendants and McKinsey used their position and access to detailed prescriber information to actually divert resources to target high volume prescribers to sell more opioids.

71. Distributors of controlled substances have a legal duty to report suspicious orders, and to report those that deviate substantially from a normal pattern and orders of unusual size and frequency. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b). These obligations included a legal duty to maintain effective controls and procedures to guard against diversion of controlled substances and a legal duty to maintain a system to identify and report suspicious orders of controlled substances. *See* 21 C.F.R. §§ 1301.7(a) (b); 1301.74(b). Rather than advising their registrant clients on how to comply with their legal duties to maintain effective controls to guard against diversion and how to operate a system to identify and report suspicious orders, in furtherance of the scheme, Defendants and McKinsey and the Opioid Marketing Enterprise Members used detailed data to target prescribers to increase the opioid market.

[405] CDC Guideline at 16.

72. Consistent with the Enterprise's purpose of increasing profit by deceptively marketing opioids, McKinsey was tasked with "Identifying Granular Growth Opportunities for OxyContin," conducting an "assessment of the underlying drivers of current OxyContin performance," identifying "key opportunities to drive near-term OxyContin performance," and developing "plans to capture priority opportunities."[406] Defendants assisted and collaborated with McKinsey to identify and exploit these growth opportunities and drivers of near-term performance, and implemented plans to capture these opportunities.

73. Defendants and McKinsey received physician-level sales data to develop its marketing strategy to increase OxyContin performance after Purdue's 2007 guilty plea. Rather than using this access to the granular data to avoid diversion and to prevent Enterprise members from targeting prescribers with suspicious prescribing patterns, Defendants and McKinsey used this information to help the Opioid Marketing Enterprise members push more opioids on high volume prescribers in furtherance of its schemes to defraud. The targets were chosen based on their history of prescribing high doses of opioids in large quantities.

74. One of the services the Enterprise used in furtherance of this scheme concerned the use of data to help Purdue meet its goals. Defendants and McKinsey's analysis for "Evolve to Excellence" shows that Defendants and McKinsey had detailed information from which it could discern, as could Purdue, whether a prescriber had problematic patterns suggesting operation as a "pill mill," including a shift to other opioids after OxyContin's reformulation. Yet, Defendants and McKinsey urged Purdue to target, and seek to increase the prescribing of, all of these prescribers from whom it perceived Purdue could obtain greater profits.

[406] PPLPC030000770531

75. McKinsey found that Purdue did not "focus on the highest potential docs," measured both by the number of prescriptions and reimbursement considerations.[407] A McKinsey analyst urged McKinsey to recommend Purdue target "[l]iterally, at least all" prescribers in the top 20% of prescribers, "minus another few percent who are no sees[.]" McKinsey team lead Arnab Ghatak replied that "they probably have 20% no see[], but i'd also assume there are not many high writers that are no see."[408] ("No see" prescribers are prescribers who do not accept visits from pharmaceutical sales representatives. Thus, upon information and belief, McKinsey recognized that most of the highest volume prescribers, or "high writers" of prescriptions, were willing to entertain sales visits from sales representatives.) Defendant ZS assisted McKinsey with targeting these prescribers, and Publicis assisted McKinsey with crafting messages to deliver to them.

76. The Opioid Marketing Enterprise used data for intentional targeting of high prescribers and not for diversion prevention. Defendants and McKinsey advised Purdue to raise sales of Oxycontin by focusing on high dose sales and deceptively messaging to physicians that OxyContin would improve function and quality of life. Defendants and McKinsey urged Purdue to maximize sales by dictating which prescribers its sales representatives would target. For example, McKinsey advised Purdue that it should take "specific actions" to increase sales of OxyContin, including "Prescriber Targeting" and "Turbocharg[ing] Purdue's Sales Engine." Defendant ZS's work was particularly relevant to these efforts.

77. Defendants and McKinsey targeted not just doctors but also nurse practitioners and physician assistants, with McKinsey recommending Purdue "[d]ouble down on nurse practitioners and physician assistants . . . as they represent a growing market segmentation of prescribers."[409]

[407] MCK-MDL2996-0364024
[408] MCK-MDL2996-0364267
[409] MCK-MDL2996-0303399

78. The Enterprise's scheme also explored ways to increase the amount of time sales representatives spent in the field increasing opioid sales, and prioritizing OxyContin in incentive compensation targets.[410] Again, ZS's work was particularly relevant to these efforts.

79. By April 24, 2014, the plan was working and McKinsey reported that Purdue's "sales force is selecting an increasing percentage of high-value OxyContin prescribers as targets."[411]

80. McKinsey ensured Purdue would benefit from the lessons learned by other Enterprise members, stating that "its experience with other pharmaceutical companies suggests that such a comprehensive Sales transformation program takes nine months."[412] Likewise, McKinsey recommended physician targeting to other Enterprise members, including Endo and Janssen.[413] Similarly, ZS and Publicis were also advising multiple Opioid Marketing Enterprise members at the same time.

81. By targeting physicians based on their prescribing patterns, the Opioid Marketing Enterprise was working toward the common purpose of deceptively convincing doctors to prescribe more opioids and thereby increase their own profits. By developing "Evolve to Excellence," which was implemented as a plan to "turbocharge" opioid sales, McKinsey advised that Purdue would see a greater return on its sales investment by focusing its targets, including on prescribers with alarming prescribing patterns that raised red flags they were writing "prescriptions" for non-medical use. Defendants worked for years with McKinsey to accomplish these goals. The plan aimed at boosting sales of OxyContin by targeting the highest volume opioid prescribers, which Defendants and McKinsey and the other members of the Opioid Marketing

[410] PPLPC012000437346
[411] MCK-MDL2996-0104840; PPLPC035000220406
[412] MCK-MDL2996-0187168
[413] MCK-MDL2996-0130803; MCK-MDL2996-0135713

Enterprise knew and/or should have known would result in the expansion of the illicit opioid market.

82. The Enterprise sought to grow opioid sales to prescribers who raised red flags of diversion and orders it knew or should have known were likely to be diverted or fuel an illegal market. Purdue had a legal obligation not to target these prescribers; rather, it was obligated to report their conduct to law enforcement. Yet the Enterprise used access to prescriber data not to report diversion but to enhance diversion.

Pattern of Racketeering Activity

83. Defendants and McKinsey together with the other Opioid Marketing Enterprise Members engaged in a scheme to unlawfully increase sales of opioids—and grow their share of the prescription painkiller market—through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain. As a unique consulting entity with knowledge of both the addictive properties and abuse potential of opioids and with access to data regarding internal prescribing behaviors of its targets, McKinsey perpetrated – with Defendants ongoing aid and assistance – a number of fraudulent schemes using the mails and wires, including advising Purdue to market more opioids, in higher doses, to high volume prescribers while helping Purdue avoid mandatory prescriber education regarding the risks of opioids. Defendants and McKinsey fueled the epidemic alongside their clients. Through targeted marketing that Defendants and McKinsey developed, "turbocharged," and implemented, Defendants and McKinsey substantially contributed to an explosion in the use of opioids across the United States. Defendants and McKinsey are engaged in and affect interstate commerce because they advised multiple opioid manufacturers headquartered on different states on the sale of opioid products across the United States, as alleged herein.

84. The Opioid Marketing Enterprise Members devised and knowingly carried out this illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute, and non-cancer pain. They knew that these representations deviated from the FDA-approved use of these drugs and were not supported by actual evidence. The Opioid Marketing Enterprise Members intended that their common purpose and scheme to defraud would, and did, deceive consumers, prescribers, regulators, Plaintiffs, and other intended victims and they used the U.S. Mail and interstate wire facilities with the specific intent to advance, and for the purpose of executing, their illegal scheme.

85. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain, the Opioid Marketing Enterprise Members engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

86. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the Opioid Marketing Enterprise Members hid from the consumers, prescribers, regulators, and Plaintiffs: (a) the fraudulent nature of the Opioid Marketing Enterprise Members' marketing scheme; (b) the fraudulent nature of statements made by the Opioid Marketing Enterprise Members regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

87. The Opioid Marketing Enterprise Members with knowledge and intent, to the overall objective of the Opioid Marketing Enterprise Members' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

88. Indeed, for the Opioid Marketing Enterprise Members' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This coordination was accomplished via their relationships with each other and via Defendants and McKinsey's relationships and contacts with key opioids manufacturers.

89. The Opioid Marketing Enterprise Members' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs, while simultaneously generating billion-dollar revenues and profits for the Opioid Marketing Enterprise Members. The predicate acts were committed or caused to be committed by the Opioid Marketing Enterprise Members through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

90. The Opioid Marketing Enterprise Members' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity. Defendants and McKinsey used mail and wire transmission, directly or indirectly, in furtherance of this scheme by transmitting deliberately false and misleading statements to prescribers and the public.

91. Defendants and McKinsey had a specific intent to deceive and defraud prescribers, regulators and Plaintiffs. For example, as alleged above, Defendants and McKinsey made repeated and unequivocal statements through the mails and wires that were false and misleading. For example, McKinsey advised Purdue to market OxyContin based on the false and misleading notion that the drug can provide "freedom" and "peace of mind" for its users, and concomitantly reduce stress and isolation.

92. Similarly, they caused to be transmitted through the mails and wires false and misleading statements regarding the addiction potential of opioids. Moreover, Defendants and

McKinsey had direct involvement in marketing statements and thus caused the statements to be made, notwithstanding that they knew they were false for the reasons detailed above.

93. The marketing scheme is especially egregious since the public relies on physicians as a position of trust and authority in the community regarding their health and well-being. Defendants and McKinsey intentionally deceived physicians regarding the abuse potential of opioids. It intended prescribers and the public to rely on its false statements. Defendants and McKinsey intended reliance on these false statements as it was their goal for doctors to prescribe more and higher quantities of these dangerous pills to the public. This scheme was therefore reasonably calculated to deceive not only persons of ordinary prudence and comprehension but also educated physicians in a place of high trust in the community.

94. **Predicate Acts**

95. To carry out, or attempt to carry out, the scheme, the Enterprise Members, each of whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate in, directly or indirectly, the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

96. Specifically, the Enterprise Members have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

97. The multiple acts of racketeering activity which the Enterprises Members committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

98. The racketeering activity was made possible by the Enterprise's regular use of the facilities, services, distribution channels, and employees of the Enterprise Members.

99. The Opioid Marketing Enterprise Members participated in the schemes by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

100. The Enterprise Members used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their schemes through common misrepresentations, concealments, and material omissions.

101. In devising and executing the illegal schemes, the Opioid Marketing Enterprises Members devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs and prescribers and to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

102. For the purpose of executing the illegal schemes, the Enterprise Members committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal schemes.

103. The Opioid Marketing Enterprise Members' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to the conduct described in the Factual Allegations section of this Complaint, and:

104. Mail Fraud: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

105. Wire Fraud: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

106. The Opioid Marketing Enterprise Members' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments, and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute, and non-cancer pain, with the goal of profiting from the increased sales of the Opioid Marketing Enterprise Members' drugs that occurred because consumers, prescribers, regulators, and Plaintiffs relied on the Opioid Marketing Enterprise Members' misrepresentations. These uses of the U.S. Mail or interstate wires included, inter alia:

107. Marketing materials about opioids and their risks and benefits, which the Opioid Marketing Enterprise Members sent to health care providers, transmitted through the internet and television, and published across the country, including in counties and cities and to Plaintiffs;

108. Written representations and telephone calls among the Opioid Marketing Enterprise Members and between the Opioid Marketing Enterprise Members regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of opioids for chronic, long-term pain generally;

109. E-mails, telephone calls, and written communications among the Opioid Marketing Enterprise Members agreeing to or implementing the opioids marketing scheme;

110. Communications among the Opioid Marketing Enterprise Members and between the Opioid Marketing Enterprise Members and the media regarding the publication, drafting, and dissemination of treatment guidelines as part of the Opioid Marketing Enterprise;

111. Written and oral communications directed to prescribers, the public, and Plaintiffs that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

112. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

113. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities are not obtainable (e.g., each time a McKinsey trained marketer "calls" or reached out to a physician targeted by ZS with materials designed and prepared by Publicis using the mails or wires in furtherance of the marketing scheme). Because the Opioid Marketing Enterprise Members disguised their participation in the Enterprise, and worked to keep the Enterprise's existence secret, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the Opioid Marketing Enterprise Members. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. Plaintiffs have, however, described the types of predicate acts of mail and/or wire fraud, including the specific types of fraudulent statements upon which, through the mail and wires, Defendants and McKinsey engaged in fraudulent activity in furtherance of their scheme.

114. The factual allegations in this Complaint describe multiple occasions of Defendants working to create and deliver to targeted audiences, including no-see prescribers, misrepresentations and false statements in furtherance of the scheme. Below, Plaintiffs also

describe examples of occasions on which other Opioid Marketing Enterprise Members disseminated misrepresentations and false statements to consumers, prescribers, regulators, and Plaintiffs' communities, and how those acts were also in furtherance of the scheme.

From	To	Date	Description
Purdue	Prescribers and Plaintiffs	2007	Statements that pain relief from opioids improves patients' function and quality of life in advertising and a book
Purdue	Prescribers	Continuous	Telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function
Purdue	FDA advisory committee	September 2009	Presentation prepared by McKinsey indicating that its reformulated OxyContin will deter abuse
Purdue	Prescribers and Plaintiffs	2010 onwards	Statements that the reformulated OxyContin will deter abuse and therefore doctors can continue to safely prescribe opioids
Purdue	Prescribers and Plaintiffs	2010-2020	Statements from Purdue at McKinsey's direction that opioids can provide "freedom," "peace of mind," and give patients "the best possible chance to live a full and active life"
Purdue	Prescribers and Plaintiffs	Advertising produced in 2016	Advertising from Purdue that "We sell hope in a bottle."
Purdue	Prescribers and Plaintiffs	2010 onwards	Statements that OxyContin's 12-hour dosing would allow patients to only need to take OxyContin twice a day, thus requiring fewer pills
Purdue	Prescribers and Plaintiffs	2013 onwards	Statements from Purdue at McKinsey's direction that OxyContin allowed physicians to "Individualize the Dose" and that the dose of OxyContin can safely be increased or tailored as the patients adapt to a certain dose
Endo	Prescribers and Plaintiffs	2009	Statements made on an Endo-sponsored website, PainKnowledge.com, indicating that patients who take opioids as prescribed usually do not become addicted
Endo	Prescribers and Plaintiffs	2009	Statements made on another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do not become addicted to opioid medications
Endo	Prescribers and Plaintiffs	Various	Statements in pamphlets and publications described by Endo indicating that most people who take opioids for pain relief do not develop an addiction
Endo	Prescribers and Plaintiffs	Various	Statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction
Endo	Prescribers and Plaintiffs	Various	Statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering
Endo	Prescribers and Plaintiffs	Various	Statements made on its website, PainKnowledge.com, that opioid dosages could be increased indefinitely

Endo	Prescribers and Plaintiffs	Various	Statements made in a publication entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" suggesting that opioid doses can be increased indefinitely
Endo	Prescribers	Various	Electronic and telephonic communications to its sales representatives indicating that the formula for its medicines is "crush resistant"
Endo	Prescribers and Plaintiffs	2007	Statements that pain relief from opioids improves patients' function and quality of life in advertising and a book
Endo	Prescribers	Various	Telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function
Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated
Janssen	Prescribers and Plaintiffs	2009	Statements in a 2009 patient education guide claiming that opioids are rarely addictive when used properly
Janssen	Prescribers and Plaintiffs	2009	Statements included on a 2009 Janssen-sponsored website promoting the concept of opioid pseudoaddiction
Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, advocating the concept of opioid pseudoaddiction
Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, indicating that opioid addiction can be managed
Janssen	Prescribers and Plaintiffs	2009	Statements in its patient education guide indicating the risks associated with limiting the dosages of pain medicines
McKinsey	Purdue (with prescribers as the planned target)	July 18, 2013	Discussion of McKinsey plan to increase calls to doctors' offices to fraudulently promote OxyContin, including via "phone, video and even Google like proprietary tools" [414]
McKinsey	Purdue (with prescribers as the planned target)	April 24, 2017	Plan to promote OxyContin to "no-see" physicians through "remote interactions" including presenting "brand interaction and materials" "over the phone/internet"[415]
McKinsey	McKinsey	July 14, 2013	Internal emails interpreting "the Purdue situation" and discussing OxyContin sales strategy including sales benchmarks and "focus on the highest potential docs"[416]

[414] MCK-MDL2996-0104431, at 0104442
[415] MCK-MDL2996-0104840
[416] MCK-MDL2996-0364024

McKinsey	Purdue (with prescribers as the planned target)	September 23, 2013	Evolve 2 Excellence PowerPoint planning execution of the scheme and discussing targeted performance metrics including "sales management calls per day, calls per year and adhering to target list"[417]
McKinsey	Purdue	July 30, 2013	Presentation showing "Scope of potential OxyContin growth opportunities" with proposed process including "Generate target list" and using "Reps/DMs [to] perform call planning (including refining target list)"[418]

115. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the Opioid Marketing Enterprise Members defrauded and intended to defraud consumers, prescribers, regulators, Plaintiffs, and other intended victims.

116. These were not isolated incidents. Instead, the Opioid Marketing Enterprise Members engaged in a pattern of racketeering activity by committing thousands of predicate acts in a five-year period, in the form of mail and wire fraud, and there remains a threat that such conduct will continue in the future.

117. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators, and Plaintiffs. The Opioid Marketing Enterprise Members calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the Opioid Marketing Enterprise Members understood and intended that those in the opioid distribution chain rely on the integrity of the pharmaceutical

[417] MCK-MDL2996-0316833, at 0316834
[418] MCK-MDL2996-0303399

companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the Opioid Marketing Enterprise Members' products.

118. Opioid Marketing Enterprise Members' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the Opioid Marketing Enterprise Members are distinct from the Opioid Marketing Enterprise.

119. The racketeering activities conducted by the Opioid Marketing Enterprise Members amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators, and Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by the Opioid Marketing Enterprise was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including consumers, prescribers, regulators, and Plaintiffs. The Opioid Marketing Enterprise Members have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

120. Each of the Opioid Marketing Enterprise Members aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

121. As described herein, the Opioid Marketing Enterprise Members engaged in a pattern of related and continuous predicate acts for many years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

122. The Opioid Marketing Enterprise Members' violations of law and pattern of racketeering activity directly and proximately caused Plaintiffs injury in their business and property. The Opioid Marketing Enterprise Members' pattern of racketeering activity logically, substantially, and foreseeably caused an opioid epidemic. The injuries of Plaintiff, as described herein, were not unexpected, unforeseen, or independent. Rather, as Plaintiffs allege, the Opioid Marketing Enterprise Members as a whole and, and Defendants and McKinsey in particular, knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Opioid Marketing Enterprise Members engaged in a scheme of deception that utilized the mail and wires in order to carry out the Opioid Marketing Enterprise's fraudulent scheme, thereby increasing sales of their opioid products.

123. It was foreseeable and expected that the Opioid Marketing Enterprise Members creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose and the injuries that occurred as a result.

The Enterprise Was Well Aware of Risks of Abuse Before It "Turbocharged" its Marketing Scheme.

124. These devastating results were eminently foreseeable by the Opioid Marketing Enterprise Members.

125. When Purdue pleaded guilty in 2007, it was evident that Purdue's behavior and excessive prescribing was directly linked to a drug addiction crisis that caused severe and extensive damage to America. Purdue's methods included "using aggressive marketing tactics to convince

doctors to unnecessarily prescribe opioids – frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America for decades."[419]

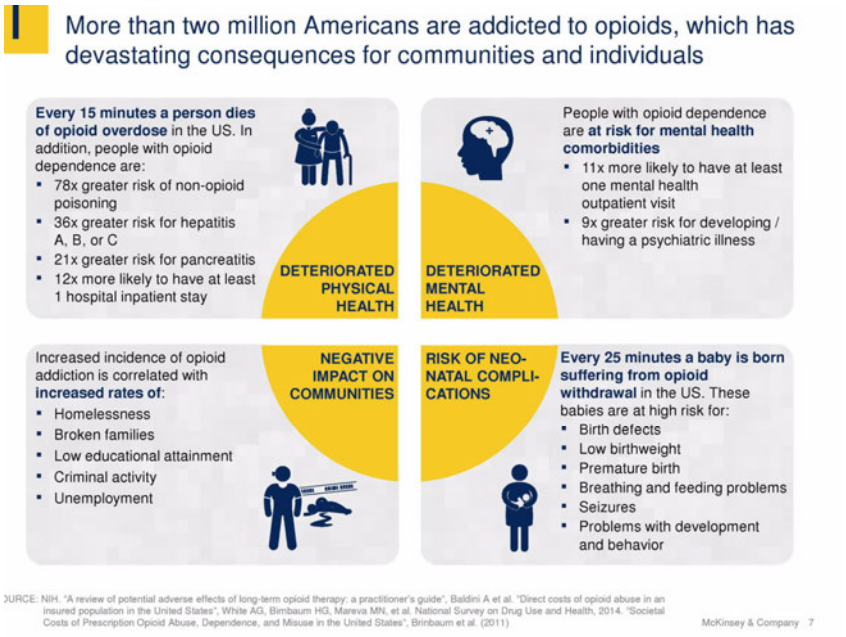
126. Defendants and McKinsey cannot deny knowledge regarding Purdue's 2007 guilty plea. At that point, McKinsey knew that opioids were addictive. McKinsey knew that OxyContin was being widely abused and causing harm to people and entities like Plaintiffs. And McKinsey knew that Purdue had been fraudulently marketing OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal. And yet, years later, in 2013, McKinsey orchestrated a scheme with Defendants to continue to aggressively promote opioids despite knowledge that people were still dying from overdoses.

127. Thus, Defendants and McKinsey continued to add fuel to this fire by persisting in aggressively marketing to physicians and continuing to fuel the opioid crisis after Purdue's guilty plea. It was foreseeable that continuing to do so would devastate American communities.

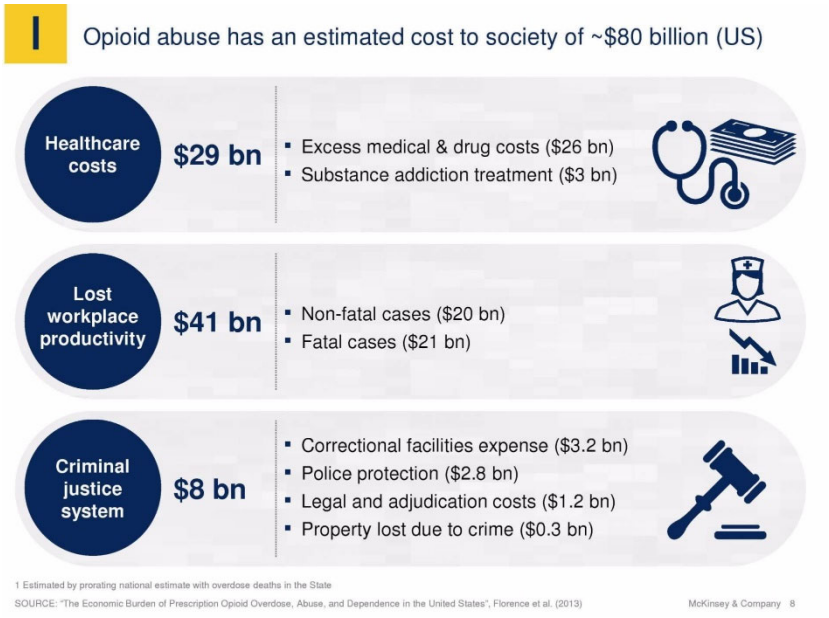
128. For example, McKinsey put together presentations highlighting the devastation of the opioids crisis. In one, McKinsey recognized that "Drug overdose fatalities far outpace car-crash deaths in the US" and a "number of underlying factors suggest there is still risk of further acceleration."[420] Similarly, a McKinsey slide show summarized what was known by 2014 about the opioid crisis, including risks of neo-natal complications and negative impacts on communities like Plaintiffs', such as criminal activity.

[419] Jan Hoffman & Katie Benner, *Purdue Pharma Pleads Guilty to Criminal Charges for Opioid Sales*, N.Y. Times (updated Dec. 17, 2020), https://www.nytimes.com/2020/10/21/health/purdue-opioids-criminal-charges.html.
[420] MCK-MDL2996-0070516, at 0070517.

129.



130. McKinsey also recognized these consequences had serious costs to society. For example, data from 2013, the same year that McKinsey launched Project Turbocharge, showed that opioid abuse had an estimated cost to society of approximately $80 billion:



131. Similarly, news stories across the nation reported additional consequences of wide scale opioid addiction: needles littered around public property, posing costs to the governments and danger to residents.[421]

132. The foreseeability of the abuse and need for additional services that would be required following the misleading marketing and increased prescribing and use of high dose opioids is also evidenced by McKinsey's attempt to put a price tag on overdoses. McKinsey suggested payment amounts for event-based contracts: $6,000 to $15,000 (paid to health insurers for increased medical services). Indeed, McKinsey was well aware that increased prescriptions would lead to overdoses and to an additional financial burden for social and health services.

133. Defendants and McKinsey are liable for their successful efforts to increase OxyContin sales after Purdue's 2007 guilty plea for misbranding the drug. Indeed, Defendants' and McKinsey's focus on increasing opioid sales after Purdue's guilty was incendiary to escalating and perpetuating the opioid epidemic by: (a) using data to specifically target high volume prescribers; (b) persuading sales of higher doses of opioids; (c) tailoring marketing messages to conceal their addictive principles; and (d) by reducing the training of sales representatives.

134. In 2013, when the consent decree expired (which obligated Purdue to submit annual compliance reports regarding its marketing), Defendants and McKinsey helped Purdue reengage in its nefarious conduct of targeting and deceiving doctors about the abuse potential of opioids.

135. After Purdue's guilty plea, Defendants and McKinsey identified physicians—that had already been influenced by Purdue's misrepresentations and were thus already high prescribers—as optimal targets for a massive marketing push to sell more OxyContin. Defendants and McKinsey monitored the prescription behaviors of individual doctors and utilized the

[421] *See, e.g.*, https://www.bostonglobe.com/metro/regionals/south/2014/10/25/hypodermic-needles-litter-landscape-south-boston/pzgmgbyjYFCD967TePDyiM/story.html

prescriber-level data and urged Purdue to allocate its time and resources to high prescribing physicians.

136. By November 2013, Defendants and McKinsey had obtained the physician-level data it had previously requested and continued to study ways to sell additional OxyContin prescriptions by refining and targeting the sales pitch to them.

137. In 2013, Project Turbocharge began. McKinsey proposed Project Turbocharge, a marketing strategy to increase opioids sales by hundreds of millions of dollars annually. With Defendants and McKinsey's ongoing aid and assistance, Purdue trained its sales representatives to operate using McKinsey's strategy for selling OxyContin to prescribers targeted by ZS and using materials and marketing tactics designed by Publicis, including disseminating misleading messages directly to prescribers via Practice Fusion. It is not coincidental to the Enterprise scheme that as soon as the constraints associated with its guilty plea and consent agreement ended, Defendants and McKinsey assisted Purdue in turbocharging sales.

138. As Defendants and McKinsey were pushing hard to turbocharge and promote the sale of opioids, McKinsey anticipated and expected that people would die from opioid overdoses. It acknowledged this when, in 2017, it proposed that Purdue pay health insurers or other entities in the distribution chain rebates "for every OxyContin overdose attributable to pills they sold."[422]

139. Defendants and McKinsey cannot deny that it was not aware of the abuse and overdose potential of opioids when it provided estimates for the future costs of overdose or opioid use disorder events.

[422] Walt Bogdanich & Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin Overdoses*, N.Y. Times (updated Nov. 5, 2021), https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html

140. Defendants and McKinsey and the other Opioid Marketing Enterprise Members marketed a product, through intentionally deceptive means, that it knew would result in consumer deaths and harm to Plaintiffs. This is not an attenuated causal chain. Rather, aggressively marketing to high prescribing individuals, and training to not fully disclose the risk of abuse, were integral parts of the marketing scheme. Publicis even described itself as the "strategic backbone" of McKinsey's Project Turbocharge initiative. Deceptive messaging to targeted prescribers who were likely to prescribe more pills in a dose with an anticipated abuse potential was part and parcel of the scheme to defraud.

141. As a result, Plaintiffs have shouldered the burden of these anticipated increased services and harm to business and property that are inherently tied to opioid abuse and misuse, and both the increased services and harms were reasonably and actually expected from increased prescribing.

142. The Enterprise's goal was to increase opioid prescribing, and the Enterprise Members knew that doing so would also result in the need for increased medical services. It was also foreseeable that increased prescriptions would also result in increased costs to Plaintiffs and communities throughout the United States.

143. But for the increase in prescribed opioids, Plaintiffs would not have to expend additional resources or suffered other harm to business and property as a result of harms associated with opioid addiction. The Enterprise persisted in targeting prescribers to prescribe high doses of opioids and knew that doing so would result in adverse health and social outcomes, including overdoses, neo-natal complications, harm to communities like Plaintiffs, hazardous waste in Plaintiffs' communities, as well as and increased expenditures on services to combat such ill effects.

Plaintiffs Have Been Damaged by the Enterprise's RICO Violations.

144. The Opioid Marketing Enterprise's misleading marketing and failure to prevent prescription opioid diversion damaged Plaintiffs. In addition to medical services, the Opioid Marketing Enterprise's misconduct has contributed to a range of social problems, including violence and delinquency. Adverse social outcomes include child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, Plaintiffs are devoting more and more resources to the opioid epidemic.

145. Notably, Plaintiffs have experienced vast harm to business and property directly, proximately, and foreseeably caused by the racketeering enterprise. The full extent of each Plaintiffs' damage cannot be fully captured in this pleading but can be fleshed out during the bellwether process. Below are some discrete examples that demonstrate the common and typical universal harm to Plaintiffs and the specific types of harm foreseeably caused by the Opioid Marketing Enterprise.

146. Specifically, the Opioid Marketing Enterprise Members' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent scheme has injured Plaintiffs in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid epidemic. The injuries to Plaintiffs, as alleged throughout this Complaint, and expressly incorporated herein by reference, include new, different, and increased expenditures by and losses to Plaintiffs, for example:

A. Hazardous waste in Plaintiffs' communities, including on Plaintiffs' real property;

B. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

C. Costs of training first responders in the proper treatment of drug overdoses;

D. Costs associated with providing first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

E. Costs associated with emergency responses by first responders to opioid overdoses;

F. Costs for providing mental health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

G. Costs associated with the injuries to the health and welfare of the residents who reside in the jurisdiction of Plaintiffs caused by the opioid epidemic;

H. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation; and

I. Losses caused by the diversion of revenue to address the opioid epidemic that would otherwise have been used to provide other services.

147. The injuries to Plaintiffs were directly and proximately caused by the Enterprise's racketeering activities because they were the logical, substantial, and foreseeable cause of the injuries to Plaintiffs. But for the opioid epidemic created by the Opioid Marketing Enterprise Members through their Opioid Marketing Enterprise, Plaintiffs would not have lost money or property, and the health and welfare of citizens would not have been harmed.

148. Plaintiffs have been injured by the Enterprise's conduct, and such injury would not have occurred but for the predicate acts which also constitute acts taken in furtherance of the

conspiracy pursuant to Section 1962(d). By working to expand the opioid market, fraudulently concealing the abuse potential of opioids, targeting high volume prescribers, and deceiving prescribers and the public in order to allow opioids to continue to remain on the market, the Enterprise caused the expansion of opioid prescribing and caused a large number of people across the United States, including in Plaintiffs' communities to become addicted to opioids, thus forcing Plaintiffs to expend, time, money and resources to address the opioid epidemic that Defendants and McKinsey and the Enterprise created through their conduct. Indeed, Defendants and McKinsey intentionally deceived doctors and public health workers in order to continue to grow the opioid market. The repeated fraudulent misstatements by Defendants and McKinsey contributed to an explosion in the use of opioids across the country.

149. Plaintiffs were direct victims of Defendants and McKinsey's misconduct. The Enterprise displayed a wanton disregard for public health and safety by intentionally deceiving doctors about the addiction potential of opioids and by marketing higher doses to physicians. The harm created by Defendants and McKinsey required Plaintiffs to expend financial and other resources to mitigate the health crisis of opioid misuse and addiction. The expansion of this market was the goal of the Enterprise and was critical to its success. Therefore, the harm suffered by Plaintiffs to their property forced them to expend resources beyond the ordinary costs of services to combat the opioid epidemic, was directly foreseeable, and in fact, was an intentional result of Defendants' and McKinsey's misconduct. Indeed, McKinsey anticipated overdose events and actually estimated price premiums on these expected overdose events. Defendants and McKinsey knew that the products it was marketing were highly addictive and could lead to deadly overdoses yet continued to "turbocharge" sales by fraudulently pushing the product on doctors through its deceptive marketing scheme.

150. The creation and implementation of the marketing scheme that Defendants and McKinsey developed and deployed through its Enterprise directly harmed Plaintiffs by imposing costs on their businesses and properties. The harm caused by this scheme was an unnatural, human-caused, profit-driven, and completely preventable disaster (had the Enterprise Members obeyed the law). Thus, Plaintiffs' injuries are not solely the result of routine government expenses. Instead, as a result of Defendants' and McKinsey's misconduct, Plaintiffs have been and will be forced to go far beyond what a governmental entity might ordinarily be expected to pay to enforce laws and to promote the general welfare in order to combat the opioid epidemic, whose primary origins were in prescription opioids administered by prescribers whom Defendants and McKinsey targeted with their marketing scheme to increase sales. This includes providing new programs and new services as a direct result and in direct response to Defendants' and McKinsey's misconduct. In addition, Plaintiffs have suffered losses to their property as a direct result of the kind of inevitable consequences of the drug addiction and criminal behavior that Defendants and McKinsey predicted. As a result of the conduct of the Enterprise, Plaintiffs have incurred and will continue to incur costs that far exceed the norm.

151. The injuries to Plaintiffs were directly and proximately caused by these racketeering activities because they were the logical, substantial, and foreseeable cause of the injuries to Plaintiffs. But for the opioid epidemic the Opioid Marketing Enterprise Members created through their Opioid Marketing Enterprise, Plaintiffs would not have lost money or property, and the health and welfare of residents in Plaintiffs' jurisdictions would not have been harmed. Moreover, Defendants' and McKinsey's internal documents show that they actually did foresee many of the harms that resulted from their conduct.

152. There are no intervening acts or parties that could interrupt the causal chain between Defendants' mail and wire fraud and Plaintiffs' injuries. Defendants, in furtherance of the Enterprise's common purpose, caused to be made false and misleading statements directly to the doctors (who consumers rely on to provide health advice) and the public. Doctors are not a break in the causal chain. Instead, the Enterprise members as a whole, and Defendants and McKinsey in particular, intentionally targeted doctors and sought to deceive them. That doctors were then deceived and behaved as the Enterprise wanted, prescribing more and more opioids, was the purpose of the scheme, not an intervening cause.

153. The Enterprise's violations of 18 U.S.C. § 1962(c) have directly and proximately caused injuries and damages to Plaintiffs, and Plaintiffs are entitled to bring this action for three times their actual damages, as well as for injunctive/equitable relief, costs and reasonable attorneys' fees and costs pursuant to 18 U.S.C. § 1964(c).

COUNT II: Negligence

154. Plaintiffs reallege and incorporate by reference the allegations set forth above.

155. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty, and the plaintiff sustained an injury or loss proximately caused by the defendant's breach.

156. Defendants, through their work with Purdue and other opioid manufacturers, owed a duty of care to the Plaintiffs', which they violated by encouraging the over-marketing and over-prescribing of a controlled substance known at the time to be addictive and known at the time to be a threat to public health.

157. In violation of this duty, for decades Defendants devised and assisted Purdue, and other opioid manufacturers, with implementing sales and marketing campaigns, including

prescriber targeting and salesforce incentive compensation structures that would dramatically increase the amount of opioids prescribed and distributed in Plaintiffs counties.

158. As a direct and proximate result of Defendants' negligent conduct, Plaintiffs have suffered and will continue to suffer harm.

COUNT III: Gross Negligence

159. Plaintiffs reallege and incorporate by reference the allegations set forth above.

160. The oversupply of opioids and plague of addiction led to a widespread epidemic of overdoses, illness, and death that claimed thousands of lives and cost many millions of dollars of public spending—circumstances that constituted an imminent or clear and present danger amounting to more than normal and usual peril.

161. Defendants, through their work with Purdue and other opioid manufacturers, owed a duty of care to the Plaintiffs', which they violated by encouraging the over-marketing and over-prescribing of a controlled substance known at the time to be addictive and known at the time to be a threat to public health.

162. In violation of this duty, for decades Defendants devised and assisted Purdue and other opioid manufacturers with implementing sales and marketing campaigns, including Purdue's *Evolve to Excellence* campaign, that would dramatically increase the amount of opioids prescribed and distributed to Plaintiffs' citizens.

163. As a direct and proximate result of Defendants' negligent conduct, Plaintiffs have suffered and will continue to suffer harm.

COUNT IV: Public Nuisance

164. Plaintiffs reallege and incorporate by reference the allegations set forth above.

165. Defendants' conduct has created a foreseeable, ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including public health, welfare, safety, peace, comfort, and convenience of the Plaintiffs' and their State Classes' communities through their work in marketing, promoting, distributing, and selling massive doses of opioids throughout the states where Plaintiffs and their State Classes are located, fueling and opioid epidemic in those communities.

166. By their conduct, Defendants knowingly exacerbated an. Opioid epidemic that affects entire communities, municipalities, towns, school districts, and states, including Plaintiffs' and their State Classes' communities. Defendants knew, or reasonably should have known, that opioids would be used, possessed, and/or diverted unlawfully nationwide, including in and around Plaintiffs' and their State Classes' school district communities.

167. Defendants nuisance-creating conduct has been intentional and unreasonable and/or violated statutes imposing specific legal requirements for the protection of others.

168. As a direct and proximate result of Defendants' intentional, unreasonable, and unlawful conduct, the Plaintiffs and their State Classes have suffered damages including, but not limited to, expenditures to provide special education and other supports and services because of learning disabilities after children's damaging exposure in utero to opioids and direct costs to Plaintiff and their State Classes for health care, disability benefits and workers' compensation.

169. By incurring pecuniary losses as a result of the increase in children born with NOWS who qualify for special education services due in part to Defendants' conduct, the Plaintiffs and their State Classes have suffered harm that is different in kind to the harm suffered by the general public in their respective states.

170. By the marketing of and efforts to boost sales of opioids in Plaintiffs' and their State Classes' communities, Defendants violated federal law including, but not limited to, 18 USC § 2 and 21 U.S.C. § 846 with respect to Purdue's violation of 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74.

171. Defendants' conduct, if unabated, will continue to threaten the health, safety, and welfare of students and staff and taxpayers of the schools of the Plaintiffs and their State Classes. The Plaintiffs and their State Classes have a clearly ascertainable right to abate this nuisance and its effects and seek relief from it.

COUNT V: Civil Conspiracy

172. Plaintiffs reallege and incorporate by reference the allegations set forth above.

173. Defendants, alongside McKinsey, worked with their opioid manufacturer clients together for decades, and agreed to commit numerous unlawful acts relating to the sale and marketing of their opioid products. Defendants and their opioid clients also agreed to use unlawful means to commit lawful acts as part of these sales and marketing efforts.

174. Defendants and their opioid clients agreed to pursue the unlawful act of knowingly misrepresenting the addictive nature of opioids in marketing their opioids to health care providers within Plaintiffs' communities.

175. Defendants and Purdue deployed the unlawful means of evading Purdue's reporting and compliance obligations to the Inspector General of the United States Department of Health and Human Services for the five years Purdue was subject to a Corporate Integrity Agreement after it pled guilty in 2007 to criminal misbranding.

176. Defendants and their opioid clients discussed herein conspired to violate state consumer protection laws. Defendants and their clients engaged in deceptive trade practices

including, making and causing to be made misrepresentations and omissions in marketing of opioids in general, and Defendants' clients' opioids, specifically, that deceived or could reasonably be expected to deceive or mislead consumers.

177. Defendants and their numerous opioid clients engaged in unfair trade practices, including, intentionally downplaying the risks, overstating the benefits, and misrepresenting the medical necessity of opioids, generally, and Defendants' clients' opioids, specifically, including for off-label uses. These practices offend established public policy and are immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.

178. Defendants knowingly made or caused to be made false or misleading representations as to the characteristics, ingredients, uses, and benefits of opioids, generally, and Defendants' clients' opioids, specifically, by downplaying the risks of addiction and abuse, overstating the efficacy, and misrepresenting the medical necessity of opioids, generally, and Defendants' clients' opioids, specifically.

179. Defendants and their numerous opioid clients agreed to deploy unlawful sales and marketing tactics to achieve the lawful purpose of maximizing ROI for Defendants' opioid clients.

180. As a consequence, Defendants are jointly and severally liable with its opioid clients for the salesforce optimization and sales and marketing practices used to promote Defendants' clients' opioid products, including Purdue's OxyContin, Teva's Fentora, Endo's Opana, Janssen's Nucynta, and others.

181. Plaintiffs were damaged as a result of the unlawful acts Defendants conspired with its clients to commit.

COUNT VI: Civil Aiding and Abetting

182. Plaintiffs reallege and incorporate by reference the allegations set forth above.

183. Defendants, alongside McKinsey, gave substantial assistance and encouragement to Purdue and their other opioid clients regarding conduct Defendants knew to be tortious and/or in violation of a duty owed by clients to third persons, including Plaintiffs'.

184. Plaintiffs were damaged as a result of the specific conduct that Defendants encouraged and substantially assisted.

551. Plaintiffs reallege and incorporate by reference the allegations set forth above.

552. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty, and the plaintiff sustained an injury or loss proximately caused by the defendant's breach.

553. Defendants', through their work with Purdue and other opioid manufacturers, owed a duty of care to the Plaintiffs', pursuant to which it would not encourage the over-marketing and over-prescribing of a controlled substance known at the time to be addictive and known at the time to be a threat to public health.

554. In violation of this duty, for decades Defendants devised and assisted Purdue, and other opioid manufacturers, with implementing sales and marketing campaigns, including prescriber targeting and salesforce incentive compensation structures that would dramatically increase the amount of opioids prescribed and distributed in Plaintiffs counties.

555. As a direct and proximate result of Defendants' negligent conduct, Plaintiffs have suffered and will continue to suffer harm.

IX. JURY DEMAND

Plaintiffs, on behalf of themselves and all others similarly situated, requests a trial by jury on all issues so triable.

X. PRAYER FOR RELIEF

Plaintiffs, individually and on behalf of the State Classes they seek to represent, respectfully pray for the following relief:

a. An order certifying the State Classes as defined above, appointing Plaintiffs as the representatives of the State Classes, and appointing their counsel as Class Counsel;

b. An award of all economic, monetary, actual, consequential, compensatory, and punitive damages available under the law, including trebling of economic injury;

c. An award of restitution and disgorgement;

d. An award of all equitable relief requested herein;

e. An award of reasonable litigation expenses and attorneys' fees;

f. An award of pre- and post-judgment interest, to the extent allowable;

g. Injunctive relief and

h. Such other and further relief as the Court deems reasonable and just.

DATED: November 5, 2024

Respectfully submitted,

/s/ Cyrus Mehri

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